

LOSE WEIGHT

LOSE 30 POUNDS IN 30 DAYS

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DECEPTION IN WEIGHT-LOSS ADVERTISING WORKSHOP:

Seizing Opportunities
and Building Partnerships
to Stop Weight-Loss Fraud



**A Federal Trade Commission
Staff Report**

December 2003



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TIMOTHY J. MURIS, Chairman

MOZELLE W. THOMPSON, Commissioner

ORSON SWINDLE, Commissioner

THOMAS B. LEARY, Commissioner

PAMELA JONES HARBOUR, Commissioner

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We are witnessing a growing epidemic of obesity in this country. This epidemic not only costs this nation over \$117 billion a year, but it also steals 300,000 lives. Unfortunately, there is no miracle pill that can help Americans lose excess weight, so we have to rely on responsible behavior – including eating right and being physically active. *The Surgeon General's Call to Action to Prevent and Decrease Overweight and Obesity*, released in December 2001, called upon almost every segment of the public and private sectors to work together to help Americans make healthy eating and physical activity choices.

By improving our nation's "health literacy" we can ensure that Americans have the information and tools they need to make effective decisions that will improve their overall health and lead to longer, healthier lives. The media can play an important role in educating consumers by providing accurate information about weight loss programs and weight management products.

In September 2002, the Federal Trade Commission staff released a report, *Weight Loss Advertising: An Analysis of Current Trends*, that found as much as 55 percent of advertising for weight loss products and services contained false or unsupported efficacy claims. Following up on that report, the FTC staff convened a workshop where representatives of the scientific community, the weight loss industry, and media trade associations discussed ways that industry and the media could reduce the spread of false promises of miraculous, fast, and effortless weight loss. This FTC staff report on the workshop lays out a number of opportunities for industry and media to assume a leadership role in addressing deceptive weight loss advertising.

The FTC staff has proposed a plan to reduce deceptive weight loss advertising that includes several segments of the community working together to promote positive, reliable messages about weight loss through advertising. A major part of the FTC staff effort is a list of seven scientifically infeasible claims frequently found in misleading weight loss ads. Advertising can play an important role in providing consumers with the information they need to make healthy weight loss choices.

I would like to thank and congratulate Chairman Muris, the other Commission members, and the staff who continue to work so tirelessly with the weight loss industry and media to promote positive, reliable messages about weight loss.

Richard H. Carmona, M.D., M.P.H., F.A.C.S.
Surgeon General
U.S. Public Health Service

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Executive Summary

This staff report (Workshop Report) provides a summary and analysis of the Federal Trade Commission's public workshop on Deception in Weight-Loss Advertising. It includes a detailed review and summary of the workshop discussion and relevant public comments submitted in conjunction with the workshop. It also sets forth the staff's recommendations for future FTC action.

The workshop, held on November 19, 2002, was a part of the FTC's effort to curb false and deceptive advertising of weight-loss products and services. The workshop followed the September 2002 release of the FTC staff report on weight-loss advertising (Weight-Loss Advertising Report). The Weight-Loss Advertising Report concluded that, despite unprecedented levels of FTC law enforcement and substantial consumer education efforts, false and deceptive weight-loss advertising was widespread. Against this backdrop, it should be noted that, according to the U.S. Surgeon General, overweight and obesity have reached epidemic proportions in the United States. As a result, at any given time, tens of millions of consumers are trying to lose weight and spending billions of dollars each year on weight loss products and services. Too often, however, these products do not provide the advertised results.

Accordingly, the goal of the workshop was to explore new approaches to stopping false weight-loss advertising. In particular, the workshop participants considered whether the FTC should compile a concise list of scientifically suspect claims found in weight-loss ads and discussed whether specific guidance identifying false claims could assist the industry and the media in eliminating false claims from weight-loss ads.

The all-day workshop consisted of three panels: science, industry, and media. The science panel, comprised of ten experts in nutrition and the study and treatment of overweight and obesity, evaluated eight weight-loss claims and considered whether the claims promised results that were not scientifically feasible. The discussion was limited to claims for nonprescription drugs, dietary supplements, creams, wraps, devices, and patches ("nonprescription weight-loss products"). Overall, the experts believed that there are certain weight-loss claims for these products that are not feasible based on the current state of the science. Based on these discussions, as well as the written comments received before and after the workshop, the published scientific and medical literature, and the

investigative experience of FTC staff, this staff report concludes that the following claims are not scientifically feasible at the current time for nonprescription weight-loss products:

- Consumers who use the advertised product can lose two pounds or more per week (over four or more weeks) without reducing caloric intake and/or increasing their physical activity.
- Consumers who use the advertised product can lose substantial weight while still enjoying unlimited amounts of high calorie foods.
- The advertised product will cause permanent weight loss (even when the user stops using the product).
- The advertised product will cause substantial weight loss through the blockage of absorption of fat or calories.
- Consumers who use the advertised product (without medical supervision) can safely lose more than three pounds per week for a period of more than four weeks.
- Users can lose substantial weight through the use of the advertised product that is worn on the body or rubbed into the skin.
- The advertised product will cause substantial weight loss for all users.
- Consumers who use the advertised product can lose weight only from those parts of the body where they wish to lose weight.*

The second panel examined whether the weight-loss industry could fashion a more effective self-regulatory program. Members of the industry favored strengthening self-regulatory guidelines and considered whether an outside group such as the National Advertising Division of the Council of Better Business Bureaus (NAD) could assist with self-regulation. Such industry-based efforts will be an important component in curbing problematic ads.

Finally, the third panel considered the media's part in disseminating problematic ads and examined the possibility of an increased role for the media in screening weight-loss ads. Panelists raised concerns regarding media screening of weight-loss ads, including various practical issues. For example, media members pointed to the short time frames available to make decisions regarding whether to run an ad and the difficulty of making judgments on whether an ad makes false claims.

* Although this report concludes that this claim is not scientifically feasible when made in the context of an ad promising substantial weight loss, it has not been included in the FTC staff's media guidance brochure ("guidance"), which is being released simultaneously with this report, because the claim does not appear to be widespread.

Having considered the panel discussions and the written comments, the FTC staff believes that guidance on scientifically infeasible claims for nonprescription weight-loss products could be useful to the industry, the media, and consumers. Industry members can incorporate information from the guidance into new or existing self-regulatory codes that can aid them in preparing truthful ads. Media outlets can compare ads they receive with the guidance and reject patently false ads before they reach the consumer. And, consumers can use the guidance in evaluating which weight-loss products they should avoid. Accordingly, the staff recommends publication of guidance that specifically identifies those weight loss claims that are not feasible based on current scientific knowledge.

At the same time, the staff will continue its other efforts to stop false and deceptive weight-loss advertising by: encouraging the media to implement viable media clearance standards and encouraging legitimate advertisers and their representatives to support this program; working with interested public and private entities to develop self-regulatory weight-loss advertising guidelines; supporting the development of effective industry self-regulatory programs; and working with private sector organizations to develop effective consumer education. In addition, the staff will recommend to the Commission that it bring enforcement actions against companies that use scientifically infeasible claims to promote weight-loss products. In any enforcement action, the Commission retains the burden of proving that the claims are false, deceptive, or unsubstantiated.

Finally, the FTC staff will continue to monitor weight-loss advertising over the course of the next year to measure improvement. Based on the results of continued monitoring, the staff will make further recommendations as are necessary and appropriate.

I. Background

Six out of every 10 Americans are overweight or obese.¹ The estimated cost of obesity exceeds \$100 billion per year.² Not surprisingly, at the same time, millions of Americans are trying to lose weight.³ The marketplace has responded with a proliferating array of products and services, many promising miraculous, quick-fix remedies.⁴ Tens of millions of consumers have turned to over-the-counter remedies, spending billions of dollars on products and services that purport to promote weight loss.⁵

To document more systematically the extent of false and deceptive weight-loss advertising, the FTC staff, with the assistance of the Partnership for Healthy Weight Management,⁶ collected and analyzed a nonrandom sample of 300 advertisements, mostly disseminated during the first half of 2001, from broadcast and cable television, infomercials, radio, magazines, newspapers, supermarket tabloids, direct mail, unsolicited commercial e-mail (spam), and Internet websites. In addition, to evaluate how weight-loss advertising has changed over the past decade, the staff compared ads disseminated in 1992 in eight national magazines with ads appearing in 2001 in the same publications.⁷

The results were released in September 2002, in a report entitled *Weight-Loss Advertising: An Analysis of Current Trends*. The report concluded that the use of false or misleading claims in weight-loss advertising was widespread. Nearly 40% of the 300 ads made at least one representation that almost certainly was false. An additional 15% of the ads made at least one representation that was very likely to be false or, at the very least, to lack adequate substantiation.⁸ The report further noted that the incidence of false weight-loss product advertising appeared to have increased over the last decade, despite an unprecedented level of law enforcement.⁹ Concurrent with the release of the report, the FTC announced that it would host a workshop to consider additional or alternative approaches to combat false and deceptive weight-loss product advertising.¹⁰

The workshop was held on November 19, 2002.¹¹ It consisted of three panels designed to consider the scientific feasibility of certain claims made for weight-loss products (the “science panel”) and to explore ways that members of the weight-loss industry and the media can contribute to curtailing weight-loss fraud (the “industry” and “media” panels).

The science panel was comprised of researchers, academics, and medical professionals from the government, academia, and private industry. Each panel member evaluated the claims and opined on whether they are scientifically feasible given the current state of knowledge and technology. The industry panel included representatives from the weight-loss industry, such as companies that sell

weight-loss products and trade associations that represent the dietary supplement industry. The panel discussed the problem that false and deceptive advertising poses for the industry, and considered how industry self-regulation could be improved. The media panel consisted of academics, media experts, and representatives of media trade associations and media outlets, and focused its discussions on the role of the media in disseminating false and deceptive weight-loss ads, as well as new approaches to effective media screening.

The workshop was productive and fostered communication among various groups about how best to address the problem of false and deceptive weight-loss advertising. To aid in this undertaking, the FTC solicited and received public comments before and after the workshop. This report provides a summary and analysis of the workshop and relevant public comments.

II. Workshop Discussion

A. The Science Panel

In its Federal Register Notice announcing the workshop, the FTC solicited comments on the creation of a list of weight-loss claims that are generally agreed to be false.¹² The notice also included a list of eight claims found in ads for nonprescription weight-loss products and requested comments on whether, given the current state of the science, these claims are false.¹³ Specifically, commenters were invited to discuss the state of the science tending to prove or disprove the claims. No comments were received prior to the workshop specifically addressing the individual claims or offering evidence to prove or disprove any of the claims. Moreover, no scientific evidence was submitted during the post-workshop comment period that suggested that, for any of the products considered, any of the subject claims could be true.

The scientific panel members – consisting of researchers, academicians, medical professionals, and industry experts¹⁴ – were each asked to consider whether certain advertising claims were scientifically feasible and the conditions that might affect the feasibility of each claim. The discussion was limited to nonprescription drugs, dietary supplements, creams, wraps, devices, and patches (“the advertised product” or “the covered products.”) The panel did not consider the feasibility of such claims for prescription drugs, meal replacement products, low calorie foods, surgery, hypnosis, or special diets such as the Atkins diet or very low calorie diets.¹⁵ Although claims made for these products or services also may be false, misleading, or unsubstantiated, including some of the claims

identified in this report, consideration of these additional products and services was beyond the limited scope of the workshop.¹⁶

The science panelists considered the following eight claims:

- The advertised product causes substantial weight loss without diet or exercise.
- Users can lose weight while still enjoying unlimited amounts of high calorie foods.
- The advertised product causes permanent weight loss.
- The advertised product causes substantial weight loss through the blockage of absorption of fat or calories.
- The user of the advertised product can safely lose more than three pounds a week for time periods exceeding four weeks.
- The advertised product that is worn on the body or rubbed into the skin causes substantial weight loss.
- The advertised product causes substantial weight loss for all users.
- Users of the advertised product can lose weight from only those parts of the body where they wish to lose weight.¹⁷

For each claim, panel members were asked individually whether they believed that the claim is feasible, given the current state of scientific knowledge. In making this determination, panelists were requested to express their individual expert opinions based upon a reasonable degree of scientific and medical certainty.¹⁸ Panelists were asked to consider theoretical and biological plausibility, scientific feasibility, possible mechanisms of action, and relevant scientific studies.¹⁹

Following a presentation on the principles of weight loss,²⁰ the panel's FTC moderator explained the framework for discussing the eight claims and said that the panelists would be polled regarding their opinions on each claim.²¹ Care was taken to ensure that the panelists understood the precise question being polled.²² In certain instances, more than one poll was taken, either because a panelist's comments suggested some misunderstanding of the question, or to test different variations of a particular claim.²³

The following sections will review the discussion of the panelists, evaluate each claim, and respond to public comments relating to the claims.

-
1. Consumers who use the advertised product can lose substantial weight without reducing caloric intake and/or increasing their physical activity.

- a. Claim

As demonstrated in the Weight-Loss Advertising Report, claims that users can lose weight without reducing caloric intake or increasing physical activity were common in weight-loss ads. Forty-two percent of the ads that the staff reviewed in the Report promised weight loss without diet or exercise, and in many cases, the claims were extreme. For example, many promised that users could lose a pound or more a day, while others claimed that users could lose three to four pounds per week, all without diet or exercise. It also appeared that these types of claims have increased over the last decade. To illustrate, none of the ads that the staff reviewed in its 1992 sample claimed that users could lose weight without diet or exercise.

Examples of this claim include, “U.S. patent reveals weight loss of as much as 28 pounds in 4 weeks... Eat all your favorite foods and still lose weight. The pill does all the work,”²⁴ and “Lose up to 2 pounds daily without diet or exercise.”²⁵

- b. Panel Discussion

Mr. Almada began the discussion by indicating that there is research on certain fibers, synthetic ephedrine and caffeine, herbal varieties of ephedra and caffeine, green tea extract, and garcinia cambogia that supports claims that users can lose weight without changing eating patterns or levels of physical activity.²⁶ Mr. Almada indicated that he thought studies supported a finding of weight loss of one pound, plus or minus a half a pound, per week, for 8 to 12 weeks.²⁷ Dr. Heymsfield examined the claim from a different perspective:

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, 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 know] 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 would cause substantial weight loss.²⁸

The panelists then discussed what the weight-loss limits would be without reducing caloric intake or increasing exercise. Dr. Heymsfield indicated that he thought the effect, if any, would certainly be less than one-half pound per week.²⁹ Dr. Wadden questioned whether even a half pound per week

would be possible.³⁰ Dr. Heymsfield advised the group that in his research on ephedrine/caffeine products, weight loss appeared to be attributable to reduction in food intake, but that there were some studies showing some very small increases in resting metabolic rates.³¹ Mr. Almada indicated that there were some studies from Europe indicating that more than half of the effect was due to appetite reduction.³² Dr. Stifler said that he believed there would be no weight loss, substantial or otherwise, for any of the covered products without reducing caloric intake or increasing exercise.³³

Following this discussion, the experts were polled. Nine of the ten experts indicated that given the current state of scientific knowledge, no nonprescription drug, dietary supplement, cream, wrap, device, or patch would cause users to lose weight without reducing caloric intake and/or increasing physical activity.³⁴ The panelists were also polled concerning their views on the same claim with the assumption that the weight loss would exceed one pound per week.³⁵ All of the experts except Mr. Almada indicated that losing more than a pound per week without reducing caloric intake and/or increasing exercise was not scientifically feasible.³⁶

c. Written Comments

A joint comment filed by the Magazine Publishers Association and the Newspaper Association of America (“Joint MPA/NAA Comment”) claims that “substantial weight loss” may mean different things to different people.³⁷ Any ambiguity about the meaning of the word “substantial” is resolved by defining it to mean more than one pound per week, as was done in the alternative formulation of the claim used in this instance.

d. Analysis

The FTC has considerable experience with claims that users can lose substantial weight without diet or exercise. For example, in *FTC v. SlimAmerica*, the FTC challenged claims that a product called *Super Formula*³⁸ could cause dramatic weight loss, including as much as 49 pounds in 29 days.³⁹ The court, after hearing from experts on both sides, concluded:

To lose one pound of weight, according to a credible expert, the average individual needs a deficit of approximately 3,500 calories between caloric intake and caloric output. Although drugs may make it easier to achieve this deficit, they cannot alter this basic equation. Thus, it would be impossible for a person who did not diet or exercise to lose weight simply by taking the defendant’s drug or weight loss product. It is thus elementary that if a person consumed calories in excess of his/her daily needs, and did not diet or exercise there would be weight increase, rather than decrease.⁴⁰

Theoretically, products purporting to cause weight loss without diet or exercise would either need to cause malabsorption of calories or to increase metabolism (so-called “thermogenic agents”). As discussed below, the number of calories that can be malabsorbed appears to be limited to 1200 to 1300 calories per week, or roughly one-third of a pound per week, at best. Accordingly, malabsorption *alone* is unlikely to lead to substantial weight loss.⁴¹

With regard to thermogenic agents, it is often difficult to evaluate the supporting evidence, given the lack of rigorous methodology in many of the studies in question.⁴² In any event, the effect of purported metabolism boosters appears to be very limited. For example, a study of green tea extract found only a 4% increase in metabolism.⁴³ Ephedrine, usually sold in combination with caffeine, has been one of the most popular thermogenic agents marketed over the past five years. It appears to produce only modest weight loss, mostly due to its appetite suppression effect.⁴⁴

The significance of the small amount of weight that can be lost through malabsorption or increased metabolism is debatable. It is clear, however, that as the amount of claimed weight loss increases, the likelihood that such weight loss can be achieved without restricting caloric intake or increasing exercise decreases dramatically. For example, weight loss in the range of two pounds per week over periods of time beyond four weeks (eight or more pounds per month) would require a net caloric deficit of 7,000 calories per week, or a 1,000 calories per day, over an extended period of time. That would amount to 40% of the total calories consumed per week on a 2,500 calorie per day diet.⁴⁵ As noted below, about 180 calories per day appears to be the outer limit for malabsorption. In addition, the staff is unaware of any scientific literature suggesting that 40% increases in metabolism can be achieved without producing toxic effects on the body.

In summary, the amount of weight loss that can be achieved through the use of nonprescription products without reducing caloric intake or increasing exercise is likely to be no more than one-fourth to one-third of a pound per week, with additional weight loss being attributable to reduced caloric intake. Accordingly, weight loss in the range of two pounds per week over periods of time beyond four weeks (eight or more pounds per month) without restricting caloric intake or increasing exercise is not now scientifically feasible.⁴⁶

-
2. Consumers who use the advertised product can lose substantial weight while still enjoying unlimited amounts of high calorie foods.

- a. Claim

Some ads go beyond merely claiming that no diet or exercise is required; these ads claim that users can lose substantial weight and still eat unlimited amounts of high calorie foods. For example, one ad stated, “Eat as much as you want, the more you eat, the more you lose, and we’ll show you how.” Another example is, “Eat All the Foods You Love and Still Lose Weight (Pill Does All the Work).”⁴⁷

- b. Panel Discussion

According to Dr. Stifler, there is an established dose response between the amount of calories consumed and the amount of weight loss (or weight gain) that results.⁴⁸ As Dr. Stifler noted: “The bottom line is you have to manage calories in order to lose weight.”⁴⁹ Dr. Hubbard agreed, saying “it is a law of physics and you cannot lose weight unless you change your energy balance.”⁵⁰ Dr. Stern observed that even a small amount of high calorie foods can have a significant effect on weight.⁵¹ Dr. Heymsfield noted, and Dr. Wadden agreed, that the claim need not be limited to high calorie foods to make it false.⁵²

Following this discussion, the panelists were polled and all the experts indicated that given the current state of scientific knowledge, no nonprescription drug, dietary supplement, cream, wrap, device, or patch would cause users to lose substantial weight while still enjoying unlimited amounts of high calorie foods.⁵³

- c. Written Comments

The Joint MPA/NAA Comment asserts that this claim may be true if the claim is interpreted to mean only that the user can eat to satiety.⁵⁴ In the case of a true appetite suppressant, a person eating to satiety might actually reduce the number of calories consumed, but this mechanism, by definition, requires calorie restriction to be successful, a fact that under FTC case law must be clearly disclosed in an advertisement.⁵⁵ Thus, an advertisement could not just claim that users can eat all they want; it also would have to convey that the product suppresses appetite and that users will not want to eat as much as before.⁵⁶ Furthermore, the staff believes that this claim, as stated and used in weight-loss ads, suggests that the user can maintain or even increase current food consumption, not reduce it.⁵⁷

d. Analysis

This claim is largely a variation of the claim that users can lose weight without reducing caloric intake or increasing exercise because the essence of the claim is that users can lose weight without reducing caloric intake and may even increase caloric intake and still lose weight. As Dr. Hubbard noted, this would defy the laws of physics. Accordingly, for the reasons set forth in the discussion of the first claim, the claim that users can lose substantial weight while still enjoying unlimited amounts of high calorie foods is not scientifically feasible.

3. The advertised product will cause permanent weight loss.

a. Claim

Forty-one percent of the ads reviewed for the Weight-Loss Advertising Report promised that the weight loss would be permanent or long-lasting. Examples of this type of claim include: “Take it off and keep it off. You won’t gain the weight back afterwards because your weight will have reached an equilibrium;” and “People who use this product say that even when they stop using the product, their weight does not jump up again.”⁵⁸

b. Panel Discussion

Dr. Yanovski started this discussion by observing:

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. . . [W]hen you remove an intervention, whether it’s eating fewer calories, increasing your energy expenditure, [or] 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 [after cessation of the intervention], that we know of, in the absence of taking in fewer calories and increasing your energy expenditures.... We also don’t know of any products or supplements that will permanently reduce appetite once the [supplement has] been discontinued.⁵⁹

Dr. Greene asked whether the claim assumed that the user discontinued using the product after weight loss had been achieved.⁶⁰ Dr. Yanovski answered affirmatively and added that she was not aware of any product for which there would not be some degree of weight regain absent lifestyle changes.⁶¹

On the issue of products that claim to cause permanent weight loss through the conversion of body fat to lean muscle mass, Dr. Greene indicated that there was no evidence that the conversion level was high enough to cause permanent weight loss.⁶² Mr. Almada noted the absence of long-term maintenance studies on over-the-counter weight-loss agents.⁶³ Following this discussion, the panelists were polled and each expert indicated that, given the current state of scientific knowledge, no nonprescription drug, dietary supplement, cream, wrap, device, or patch would cause permanent weight loss.⁶⁴

c. Written Comments

No comment suggested that there is any evidence that use of any of the covered products would result in permanent weight loss after discontinuation of the product. The Joint MPA/NAA Comment states that Dr. Stern said that long-term trials showed Xenical™ users were able to keep the weight off for years.⁶⁵ Although Dr. Stern made this statement, her next comment was “when you stop using the medication, weight is regained. There isn’t anything permanent about that weight loss.”⁶⁶ Dr. Yanovski agreed.⁶⁷

The Joint MPA/NAA Comment also asserts that this claim could be true if the person continued using the product.⁶⁸ Assuming that such a claim could be true, the claim set out above contains no such qualification.⁶⁹ It is the staff’s view that if an advertisement claims that weight loss is permanent and does not convey that continued use is required, a significant proportion of consumers will reasonably interpret the ad to mean that they will not regain the weight even if they discontinue use of the product.⁷⁰

d. Analysis

As noted in the discussion of the experts, assuming a product causes weight loss through a reduction of calories, through either an appetite suppression or malabsorption mechanism, weight would be regained once the intervention stops and calorie consumption returns to pre-intervention levels. In fact, it is well established that most people who lose weight gain it back within five years. Experts have repeatedly observed that although persons generally lose weight while actively participating in treatment, they tend to regain the weight over time once treatment ends.⁷¹ According to the National Academy of Science, Food and Nutrition Board, “Many programs and services exist to help individuals achieve weight control. But the limited studies paint a grim picture: those who complete weight-loss programs lose approximately 10 percent of their body weight only to regain two-thirds of it back within 1 year and almost all of it back within 5 years.”⁷² Finally, no long-term studies on the weight loss maintenance of any of the covered products have been brought to the staff’s

attention, and we are not aware of any such studies in the published literature.⁷³ Accordingly, a claim that a nonprescription drug, dietary supplement, cream, wrap, device, or patch can cause permanent weight loss is not scientifically feasible.⁷⁴

4. The advertised product will cause substantial weight loss through the blockage of absorption of fat or calories.

a. Claim

This claim has been highly popular over the last four years. Like other claims, it implies that users do not have to control what they eat, that the product will take the place of willpower. An example of this 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.” Another example is, “The Super Fat Fighting Formula inhibits fats, sugars and starches from being absorbed in the intestines and turning into excess weight, so that you can lose pounds and inches easily.”⁷⁵

b. Panel Discussion

Dr. Stern started the discussion by considering what it would take to lose one pound a week, two pounds a week, and two pounds daily through the malabsorption of fat:

And in terms of calories, to lose one pound a week, it would take malabsorption of about 500 calories a day or about 55 grams of fat. To lose two pounds a week, it would take malabsorption of about 1,000 calories or about 110 grams of fat. And to lose two pounds daily, it would take malabsorption of more than 7,000 calories and that would be about 750 grams of fat daily.⁷⁶

According to Dr. Stern, even with Xenical™, a prescription drug causing malabsorption of fat, users do not malabsorb more than about a third of their fat calories because, above that level, there are significant gastrointestinal effects. Based on the Xenical™ research, Dr. Stern concluded that users could not malabsorb 55 grams of fat a day, the amount necessary to lose a pound a week.⁷⁷ In addition, Dr. Stern noted that her studies of chitosan, a popular ingredient in over-the-counter fat blockers, showed no significant fat malabsorption.⁷⁸

The panel discussed whether, for the purposes of this claim, “substantial weight loss” should be defined as a pound a week.⁷⁹ The panel decided that it was not necessary, given the unlikelihood that more than 20 grams of fat per day (about 180 calories) could be malabsorbed.⁸⁰ As Dr. Yanovski summed up the panel’s discussion:

I think it's... important [to note] that this is not to say that medications... such as orlistat [Xenical™] don't work in terms of decreasing fat absorption. They clearly do. But the amount of calories lost [via this mechanism] is really modest, and... 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.⁸¹

Each expert on the panel expressed the view that substantial weight loss through malabsorption of fat or calories alone is not currently scientifically feasible.⁸²

c. Written Comments

The Joint MPA/NAA Comment suggests that all of the experts agreed that a fat absorption pill can effectively reduce weight and that the only issue was what constitutes “substantial weight loss.”⁸³ On the contrary, given the modest effects of even the acknowledged fat blockers like Xenical™, the experts found it unnecessary to define “substantial weight loss” to conclude that the claimed results are not scientifically feasible.⁸⁴ Products such as Xenical™ must be used in conjunction with dietary restriction to produce substantial weight loss, *i.e.*, the malabsorption mechanism alone is not sufficient.⁸⁵

d. Analysis

The biological facts do not support the possibility that sufficient malabsorption of fat or calories can occur to cause substantial weight loss. To lose even one pound per week would require the malabsorption of about 500 calories a day or about 55 grams of fat.⁸⁶ To lose two pounds per day, as stated in the sample ad, would require the malabsorption of 7000 calories per day, which is impossible given that it is several times the total calories that most people consume on a daily basis, let alone the number of calories consumed from just fat.⁸⁷

The FTC has challenged a number of deceptive fat blocker claims for some of the most popular diet products on the market,⁸⁸ and the evidence supports the position that consumers cannot lose substantial weight through the blockage of the absorption of fat.⁸⁹ Based on its past experience, as well as the discussion at the workshop, written comments, and published studies, the staff concludes that the claim that a nonprescription drug, dietary supplement, cream, wrap, device, or patch will cause substantial weight loss through the blockage of absorption of fat or calories is not scientifically feasible.

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5. Consumers who use the advertised product can safely lose more than three pounds per week for a period of more than four weeks.

- a. Claim

Some weight-loss advertisements claim that the advertised product (sometimes in conjunction with a diet or exercise program) can cause a user to lose safely more than three pounds per week over multiple weeks or months. In some cases, the safety and efficacy claims are contained in the same phrase; at other times, the two claims are made in separate sentences. In both cases, the ads convey the message of rapid, substantial, and safe weight loss. Examples of this claim include, “Lose three pounds per week, naturally and without side effects,” and “Our product is safe and effective,” with a customer testimonial claiming more than 12 pounds of weight loss per month. With regard to this claim, the ad does not claim that the products are being used under medical supervision.

- b. Panel Discussion

Dr. Heymsfield started the discussion of this claim and noted that very low calorie diets, *i.e.*, less than 800 calories per day, produce weight loss in the range of two to four pounds per week.⁹⁰ These diets entail certain risks and should only be followed under medical supervision.⁹¹ Based on risk factors and taking into account initial water loss caused by a low-calorie diet, Dr. Heymsfield concluded that the safe rate of weight loss would be about 10 pounds per month.⁹² According to Dr. Stiffer, there could be a different threshold for what is considered safe weight loss, depending on whether the person is under medical supervision, the size of the person, the content of the diet, and other relevant risk factors.⁹³ In response, Dr. Hubbard indicated that onset of symptomatic gallstones is a risk associated with rapid weight loss, and observed:

[T]here 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 [reasonably] safe for the general population that is not seeking any type of medical advice.⁹⁴

Dr. Wadden indicated that although it is possible to lose three pounds per week on certain diets, it is not something that individuals can do safely on their own, pointing out that in the 1970s, 59 people died from using a popular liquid protein diet.⁹⁵

The panel discussed whether the amount of weight loss should be expressed in percent of initial body weight or number of pounds. It was decided to poll the panel based on the question as initially presented, because three pounds per week would cover most people.⁹⁶ In addition, it was assumed

that the claim involved use of a product without medical supervision.⁹⁷ All of the experts indicated that the claim was not scientifically feasible at the current time.⁹⁸

c. Written Comments

The Joint MPA/NAA Comment points out that several of the experts cited examples of individuals safely losing more than 12 pounds per month.⁹⁹ Although anecdotal experiences were discussed, the panel examined the question of whether losing more than three pounds per week over a month or more, unsupervised by medical professionals, is reasonably safe for the general population.¹⁰⁰ The panelists indicated that it is not.

d. Analysis

There are significant health risks associated with medically unsupervised, rapid weight loss over extended periods of time.¹⁰¹ This conclusion does not mean that every person who loses more than three pounds per week will suffer serious side effects, but it does mean that weight loss in this range can create medical risks. In general, “the more restrictive the diet, the greater are the risks of adverse effects associated with weight loss.”¹⁰² One of the best documented risks is the increased incidence of gallstones.¹⁰³ Added to this risk is the fact that some very low calorie diets¹⁰⁴ can be nutritionally inadequate and result in serious injury or even death.¹⁰⁵ Based on the discussion at the workshop, written comments, and the published literature, the claim that consumers who use one of the covered products without medical supervision can safely lose more than three pounds per week for a period of more than four weeks is not scientifically feasible.

6. Users can lose substantial weight though the use of the advertised product that is worn on the body or rubbed into the skin.

a. Claim

The products at issue for this claim include creams, wraps, patches, earrings, shoe inserts, and rings, among others, that can be purchased without a medical prescription. Examples include, “Lose two to four pounds daily with the Diet Patch,” and “Thigh Cream drops pounds and inches from your thighs.”

b. Panel Discussion

Dr. Blackburn began the discussion by expressing his view that it was not currently scientifically feasible to apply dermal transmission technology to the area of weight loss.¹⁰⁶ Mr. Almada disagreed

on whether it was technologically feasible, but noted that such a product would constitute an unapproved drug.¹⁰⁷ On the feasibility issue, both Mr. Almada and Dr. Blackburn noted that there were a number of significant technical issues involved in transdermal delivery that have not been solved as of now.¹⁰⁸

Some products in this category, *e.g.*, weight-loss earrings and shoe inserts, purport to work through the principle of acupressure. Dr. Stern indicated that a research study conducted by George Bray found that an acupressure earring was not effective.¹⁰⁹

The panel of experts was polled following the discussion. All ten of the experts indicated that a claim that a product worn on the body or rubbed into the skin causes substantial weight loss is not scientifically feasible.¹¹⁰

c. Written Comments

The Joint MPA/NAA Comment notes that the experts generally saw transdermal delivery as a biologically plausible delivery system but fails to mention that the experts believed that delivery of an active ingredient in sufficient quantities to cause substantial weight loss is not scientifically feasible at the current time.¹¹¹

d. Analysis

Since 1990, the Commission has challenged numerous products in this category, including acupressure devices, skin patches, slimming insoles, body wraps, and creams.¹¹² The Commission's complaints alleged that efficacy claims for these products were not supported by reliable scientific evidence. Similarly, no such evidence was submitted during the workshop comment period.

Some products in this category purport to work through the principle of acupressure, but the biological plausibility of such an effect on body weight appears suspect.¹¹³ Moreover, substantial weight-loss claims for creams are not scientifically feasible.¹¹⁴ Finally, the studies on topical lipolytic treatments such as aminophylline do not show substantial weight loss.¹¹⁵

Products that rely on skin patches to deliver the purported active ingredient for weight loss are biologically plausible but not, at this time, scientifically feasible. As noted during the panel discussion, the technical issues involved in transdermal delivery are significant.¹¹⁶ In addition, it should be noted that no transdermal weight-loss or weight-control products have been approved by the FDA. Thus, so called diet patches are unapproved drugs and their introduction into commerce is prohibited.¹¹⁷

Based on the investigative experience of FTC staff, as well as the discussion at the workshop, written comments, and the published literature, a claim that users can lose substantial weight through the use of the advertised product that is worn on the body or rubbed into the skin is not scientifically feasible.

7. The advertised product will cause substantial weight loss for all users.

a. Claim

This claim can be made in a variety of ways. For example, the statement, “Lose excess body fat. No willpower required. Works for everyone no matter how many times you’ve tried and failed before,” conveys this claim.¹¹⁸

b. Panel Discussion

The panelists thought this claim was problematic for several reasons. Dr. Heymsfield noted that only about one-third to one-half of people even respond to prescription drugs like Phentermine, Meridia™, and Xenical™.¹¹⁹ Dr. Greene added that rates of weight loss will vary because individual metabolic rates vary.¹²⁰ According to Dr. Blackburn, even surgery does not have a 100% success rate.¹²¹

Mr. Almada raised the issue of whether it would be possible to minimize non-responders through gene therapy, but conceded that such therapy is not available at the current time.¹²² Dr. Stern indicated that such developments were probably five to ten years in the future, and Dr. Hubbard said that even gene therapy was unlikely to work for all people.¹²³

In response to Dr. Stifler’s statement that a restricted calorie diet will cause weight loss in all people, the panel was reminded that only nonprescription drugs, dietary supplements, creams, wraps, patches, and similar articles were being considered.¹²⁴ Dr. Yanovski pointed out that products that require users to take in fewer calories will work only for those who follow the dietary regimen.¹²⁵ At this point, the panelists were advised that they should focus on whether the product itself is capable of producing the claimed benefit.¹²⁶ Dr. Wadden summarized this part of the discussion:

[W]henver 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 about 10 pounds, with a product, you will have a distribution such that about 15 percent of individuals who receive the product are going to lose less than three or four pounds. This is just the 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.¹²⁷

Dr. Greene agreed, noting that in biological systems, “it’s never all.”¹²⁸

The panel then discussed whether it was necessary to use the word substantial, and, if so, whether the term needed to be defined. The sense of the panel was that to be conservative, the term should be retained and it did not need to be defined.¹²⁹ The panel was then polled. Each expert indicated that, given the current state of scientific knowledge, no nonprescription drug, dietary supplement, cream, wrap, device, or patch would cause substantial weight loss for every user.¹³⁰

c. Written Comments

The Joint MPA/NAA Comment states that several panel members expressed the view that this claim could be true and that one expert said the claim was scientifically feasible.¹³¹ The discussion cited, however, was of low calorie diets, which can lead to weight loss.¹³² The claim makes no reference to restricted caloric intake, however, and none should be assumed.¹³³ Moreover, what is theoretically possible may not be scientifically feasible. One expert did express the view that this claim might be theoretically possible and gave gene therapy as an example, but even that expert indicated that the claim is not scientifically feasible at this time.¹³⁴

d. Analysis

Although there are common characteristics among the relevant population, there is not a single cause of overweight or obesity. In some people, the cause may be more closely linked to genetic factors while in other instances, the principal causal factor may be environmental.¹³⁵ Moreover, it should be obvious that diets, metabolic rates, and levels of physical activity vary from one individual to another and that compliance levels will vary.¹³⁶ Even approved drugs for weight loss always have a high level of non-responders, and even gastric surgery for obesity is not successful 100 percent of the time.¹³⁷ Based on the discussion at the workshop, written comments, and published literature, a claim that a nonprescription drug, dietary supplement, cream, wrap, device, or patch will cause substantial weight loss for all users is not scientifically feasible.

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8. Consumers who use the advertised product can lose weight only from those parts of the body where they wish to lose weight.¹³⁸

a. Claim

This claim targets users who want to lose substantial weight, but only from selected parts of their body, *e.g.*, users who want to lose a lot of weight from their abdomen, thighs, hips and/or buttocks, but nothing from their breasts. For example, the following testimonial makes this claim: “And it has taken off quite some inches from my butt (5 inches) and thighs (4 inches), my hips now measure 35 inches. I still wear the same bra size though. The fat has disappeared from exactly the right places.”

b. Panel Discussion

According to Dr. Wadden, even if some products may cause more weight loss from certain areas of the body than others, no parts will be spared completely. Dr. Wadden explained it this way:

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.¹³⁹

Panel members spent some time discussing research on aminophylline cream.¹⁴⁰ Mr. Almada noted that this cream, developed by George Bray and Frank Greenway, purports to cause spot reduction.¹⁴¹ Dr. Wadden noted that the research did not show fat loss in the thighs,¹⁴² and Dr. Stern added that her efforts to replicate the research with a comparable cream were unsuccessful.¹⁴³

Several panelists expressed the view that regional fat loss may be theoretically possible, but is not now scientifically feasible.¹⁴⁴ Finally, Dr. Heymsfield noted that the absence of recent studies is a good indication that the technology for spot reduction creams is not available at the current time.¹⁴⁵ Following this discussion, the panel was polled; nine of the ten experts indicated that given the current state of scientific knowledge, no nonprescription drug, dietary supplement, cream, wrap, device, or patch would cause users to lose weight only from those parts of the body where they wish to lose weight.¹⁴⁶ Mr. Almada was uncertain as to whether the claim was scientifically feasible.¹⁴⁷

c. Written Comments

The Joint MPA/NAA Comment asserts that several of the experts could not state unequivocally whether the claim was true or false.¹⁴⁸ The Joint MPA/NAA Comment, however, refers to the

experts' discussion of biological plausibility rather than scientific and technical feasibility. With the exception of Mr. Almada, the experts considered this claim not to be scientifically feasible at the current time.¹⁴⁹

d. Analysis

Panel members spent some time discussing research on aminophylline cream. According to published studies, aminophylline cream may cause the redistribution of fat from the thigh area to all other fat stores.¹⁵⁰ It is important to note that the published studies on aminophylline measure girth in the thigh area; they do not measure fat loss. The studies are small (5-23 subjects) and of relatively short duration (4 to 6 weeks). Moreover, the differences between the treatment and the controls are extremely small.¹⁵¹ Under these circumstances, it is understandable that the authors described the treatment as cosmetic.¹⁵² There has been little other published research in this area and the results do not appear to be consistent.¹⁵³

Based on the discussion at the workshop, written comments, and the analysis set forth above, a claim that a nonprescription drug, dietary supplement, cream, wrap, device, or patch can cause users to lose weight only from those parts of the body where they wish to lose weight is not scientifically feasible at this time. Nevertheless, the staff has reviewed the advertisements collected for the Weight-Loss Advertising Report and found that this claim does not appear to be widespread. Moreover, omitting this claim from the FTC staff's media guidance brochure will simplify the guidance.¹⁵⁴ For these reasons, the claim is not included in the guidance.

In summary, the panel's discussion supported the view that there are certain weight-loss claims that could be determined, on their face, to be scientifically infeasible. This discussion provided a foundation for the industry and media discussions concerning how such information might be used to curtail false weight-loss advertising.

B. The Industry Panel

The second workshop panel considered how weight-loss industry members can help reduce weight-loss advertising fraud. On the panel were representatives of three dietary supplement trade associations and two companies that sell weight-loss and fitness products. The panel also included representatives of the Electronic Retailing Association ("ERA"), the Partnership for Healthy Weight Management, and the National Advertising Division of the Council of Better Business Bureaus ("NAD").¹⁵⁵ Panelists discussed the role the industry could play in ensuring that weight-loss products and services are advertised truthfully. The panel concluded that trade associations and other industry

members – alone and in conjunction with other groups – can contribute to more effective self-regulation of false and deceptive weight-loss ads. This section summarizes the discussion of the industry panel, with an emphasis on the damage false and deceptive ads cause the industry, existing and new means of industry self-regulation, the potential for an outside group like NAD to assist with the self-regulatory process, and the possibility of creating partnerships involving the media to help reduce false ads.

1. False and Deceptive Ads Tarnish Reputable Marketers

Industry panelists expressed concern about the negative effects false and deceptive weight-loss ads have on reputable companies. According to panelists, truly false ads are not difficult to spot. For example, the National Nutritional Foods Association (“NNFA”), a dietary supplement trade group, noted that weight-loss products are one of the fastest-growing segments of the dietary supplement industry,¹⁵⁶ and some weight-loss ads are “clearly ‘over the line.’”¹⁵⁷ The Electronic Retailing Association, which represents direct response advertisers including infomercial producers, felt there was ambiguity about some of the eight claims discussed, but agreed that certain weight-loss claims are, on their face, obviously false.¹⁵⁸ ERA’s panelist stated that “[w]hen you see an egregious outlier, I think it is self-evident that it’s really bad.”¹⁵⁹ She added, “I don’t think anybody in the room looked at the two shows this morning and said, well, those claims could be true.”¹⁶⁰ In addition, she noted that one of the ads described in the Weight-Loss Advertising Report claims users can lose up to seven pounds of fat a day, and she didn’t think anyone would find that not egregious.¹⁶¹ On a similar note, the panelist from the Council for Responsible Nutrition (“CRN”), a dietary supplement trade group, questioned how anyone can be “so gullible” in the face of such obviously false ads.¹⁶²

Panelists agreed that the entire industry suffers because of false and deceptive ads. Companies that advertise truthfully and responsibly may be at a disadvantage compared to less scrupulous sellers.¹⁶³ These reputable companies are forced to compete with advertisers who do not play by the rules.¹⁶⁴ In addition, responsible companies’ images may be tarnished simply by the presence of unrealistic claims in the marketplace. Jenny Craig’s representative expressed concern that others “damage both the industry and us unfairly” when they promote quick-fix solutions.¹⁶⁵ ICON Health & Fitness’s (“ICON”) panelist also lamented “magic bullet” claims in weight-loss ads, which hinder responsible companies’ efforts to legitimize the industry and encourage lifestyle changes.¹⁶⁶

Similarly, trade associations voiced concern about marketers who make false, deceptive, and unsupported claims. CRN has been interested in this area for some time,¹⁶⁷ and the American Herbal Products Association (“AHPA”), representing marketers of herbal dietary supplements, has met with

FTC staff to discuss weight-loss advertising issues.¹⁶⁸ One of the primary concerns of these groups, as ERA articulated, is that “fraudulent and unscrupulous” weight-loss ads undermine consumer confidence in the industry, which hurts everyone.¹⁶⁹ The NNFA agreed that the entire industry, even manufacturers who conscientiously obey the law, “pay the price” when the consumer is misled.¹⁷⁰

Panelists expressed support for the Commission’s ongoing efforts to prosecute marketers who make false and deceptive weight-loss claims. Several groups believe increased law enforcement is an important component in fighting problematic weight-loss ads, and should be a continued area of the FTC’s focus.¹⁷¹ AHPA emphasized the continued need for specific enforcement actions.¹⁷² NNFA favored more enforcement specific to Internet advertisements, and Jenny Craig’s representative concurred that law enforcement is key.¹⁷³ At the same time, however, panelists acknowledged that law enforcement alone is not enough.¹⁷⁴ AHPA’s representative said the groups at the workshop know this, and attended precisely to explore alternative approaches to reducing deceptive weight-loss claims.¹⁷⁵ Other panelists indicated they are similarly open to considering new ways to fight the proliferation of misleading weight-loss claims.¹⁷⁶

2. Industry Self-Regulation

One of the panel’s main objectives was to consider how to strengthen industry self-regulation for false and deceptive weight-loss ads. Several industry associations already have in place some mechanisms for self-regulation.¹⁷⁷ In particular, most have some sort of code or voluntary guidelines that address issues related to product advertising.¹⁷⁸ These existing guidelines, however, apply to all products advertised or sold by association members (not just weight-loss) and therefore may be inadequate to address the special concerns and considerations associated with weight-loss ads.

At the workshop, the trade associations described their existing self-regulatory programs. ERA said it requires members to certify that their infomercials meet the association’s formal guidelines.¹⁷⁹ These guidelines generally mirror what the law already requires.¹⁸⁰ If ERA receives a complaint about a certified infomercial potentially violating the guidelines, it refers the program to a five-member review board.¹⁸¹ If the board agrees the program is in violation, the show is sent to NAD for a formal review.¹⁸² Similarly, NNFA has guidelines for how members should market their products.¹⁸³ NNFA’s code of ethics describes the association’s policies for marketing and selling products and must be signed by members each year.¹⁸⁴ In addition, NNFA has quality assurance programs for suppliers, and those who do not meet the requirements may not be members of the organization.¹⁸⁵ Finally, CRN’s code of ethics addresses in general terms issues of product quality, product formulation, advertising, and substantiation.¹⁸⁶

Panelists recognized, however, that current self-regulatory programs vary in effectiveness. ERA has had some success in enforcing its guidelines and bringing offending infomercials to the attention of NAD.¹⁸⁷ But the formal review process can be resource-intensive and lengthy, and is therefore reserved for only what are considered outliers among infomercial shows.¹⁸⁸ In addition, the time delay that can occur between initiating an investigation and resolving the case – time during which the infomercial continues to air and consumers continue to buy the product – can have costly consequences in a direct-response industry.¹⁸⁹ As a result, ERA was considering hiring an ombudsman who could more routinely and systematically review and correct its members’ ads.¹⁹⁰ CRN, on the other hand, does not formally monitor members’ ads or actively enforce advertising guides.¹⁹¹ Consequently, for its members, the consequences of false or deceptive advertising may be low.¹⁹² CRN’s representative acknowledged that his association is not “a police force” for members and does not have “a lot of teeth” in regulating members’ ads.¹⁹³

The panel also discussed the development of advertising guidelines specific to weight-loss products, given that existing industry guidelines do not adequately address weight-loss ads.¹⁹⁴ As described at the workshop, AHPA is in the process of developing draft advertising guidelines for weight-loss dietary supplements.¹⁹⁵ AHPA’s guidelines will be tailored specifically to stand-alone supplements, and will likely specify what information should and should not be included in weight-loss ads.¹⁹⁶ For example, the guidelines might say ads should disclose product ingredients and emphasize the need for diet and exercise, but avoid the use of before-and-after pictures or claims that imply rapid results.¹⁹⁷ NNFA, CRN, and ERA all expressed support for the development of industry guidelines that can educate marketers and assist them in lawfully advertising weight-loss products.¹⁹⁸ CRN’s representative also discussed CRN’s red-yellow-green light guidelines for the marketing of sports nutrition products to youths as a possible model for weight-loss advertising guidelines.¹⁹⁹

Along with exploring industry-based guidelines, panelists debated the usefulness of having guidance on scientifically suspect claims. Most groups supported some sort of guidance; however, there were reservations about the publication of a specific list of claims. Dietary supplement associations generally felt the FTC was on the right track and guidance on advertising claims could be beneficial. CRN agreed with “the philosophy” of publishing a list, as long as the guidelines or criteria are clear.²⁰⁰ AHPA voiced a concern about the science panel’s lack of sufficient representation from the sector of the industry that supports dietary supplements and self-care.²⁰¹ But its representative was receptive to the idea of the proposed guidance and believed the eight claims identified by the science panelists “all need to be addressed” in some fashion.²⁰² NNFA was “very much in favor” of the

proposal to publish a list of scientifically suspect claims, with the examples and guidelines discussed on the science panel, and would like to see that “progress and be published as soon as possible.”²⁰³

The ERA representative, however, raised certain objections to the publication of a list of problematic claims. She questioned the reliability of a list, arguing that science is emerging and not static.²⁰⁴ For this reason, she argued, ads must be examined solely on a case-by-case basis.²⁰⁵ The ERA representative also feared that with a list, context and “net impression” of ads would be overlooked.²⁰⁶ She said that except for the claim that you can lose weight without diet and exercise, she could see a context in which each of the other claims could be made with appropriate disclaimers.²⁰⁷ Therefore, she said, the case-by-case approach is best.²⁰⁸ In response, the Partnership for Healthy Weight Management representative, a medical doctor who participated on the science as well as the industry panel, explained that the eight claims were considered by the science panel in an unqualified state, without disclaimers.²⁰⁹ He asserted that if found in weight-loss ads, without qualifiers, the claims must be deemed scientifically unsound.²¹⁰

NNFA, while supportive of the proposed guidance, was concerned that a list of what it characterized as “presumptively false claims” might be too narrow, and that marketers would interpret any claim not specifically listed as being allowed.²¹¹ Because a list can never be all encompassing, it asserted, a problematic claim not on the list may be misunderstood as permissible.²¹²

3. The Role of the National Advertising Division of the BBB

Another area explored was whether an outside third party such as NAD – the advertising self-regulatory arm of the Council of Better Business Bureaus – can contribute to an improved self-regulatory process for the weight-loss industry.²¹³ The panel member from NAD described the group’s existing system through which companies can challenge competitors’ ads.²¹⁴ She explained that NAD’s voluntary system is not designed to punish, but rather to ensure the truthfulness and accuracy of advertisements.²¹⁵ The process begins when a challenger contacts NAD to complain about certain advertising, and questions whether the advertiser has support for its claims.²¹⁶ The challenger may also submit evidence that tends to disprove the claims.²¹⁷ The advertiser is then notified and invited to participate in the process, which involves NAD conferring with each side about what messages the ad conveys, whether it can be interpreted more broadly than intended, and whether there is appropriate substantiation to support the claims.²¹⁸

Industry members were interested in the possibility of involving NAD in a self-regulatory process targeted to weight-loss ads. Some associations had engaged in pre-workshop discussions with NAD about a potential role. For example, NNFA contacted NAD to explore how NAD’s self-regulatory

model could be incorporated into the association's membership requirements.²¹⁹ CRN discussed with NAD how an outside third party could be of use in weight-loss advertising regulation.²²⁰

Companies on the panel, however, expressed concern that NAD's existing process may not be well-suited to addressing false and deceptive weight-loss ads. They were not convinced that NAD can be effective in this area. NAD conceded that businesses have been slow to bring competitor complaints about weight-loss products and dietary supplements as a whole.²²¹ Its panelist opined that this may be because nobody wants to "test the waters or make waves or find out where the bright lines are."²²² Jenny Craig and ICON, however, cited as the reason skepticism about what the system can do. Jenny Craig questioned how much NAD can accomplish in this area,²²³ and ICON was skeptical about NAD's ability to reach the worst offenders.²²⁴ As ICON's panelist explained, some of the most problematic ads are produced by small, overseas companies that have no property, presence, or permanency in the United States, and nothing at risk here.²²⁵ These entities defraud consumers and disappear before they are caught.²²⁶ They are not legitimate businesses, have no incentive to participate in any voluntary self-regulatory program, and are thus effectively beyond NAD's control.²²⁷

NAD acknowledged these concerns and confirmed that some entities are not good candidates for self-regulation.²²⁸ With respect to companies that are not legitimately based in this country, or have no truthful claims to make about their product, it is not a good process.²²⁹ Another concern raised about using the existing NAD system was that companies do not always have the extra resources to devote to reviewing competitor ads and preparing formal complaints for NAD. Jenny Craig's representative said this is an issue for his company which, like any other, must decide how best to allocate its resources.²³⁰ An additional issue, raised by ERA and acknowledged by NAD, was the length of time the formal review process can take.²³¹

To surmount some of these hurdles, the panel considered the idea of creating a special unit within NAD (not unlike the Children's Advertising Review Unit) that could review weight-loss ads less formally and on a faster track.²³² NAD was open to discussing such a unit, but acknowledged that funding it might be a challenge.²³³ Association representatives acknowledged difficulty in getting financial support from their members for any new initiatives.²³⁴ Most agreed, however, that depending on the specifics of the program, they could see encouraging members to fund a viable self-regulatory process targeted to deceptive weight-loss ads.²³⁵

4. The Creation of a Partnership Involving the Media in Self-Regulation

The panel also considered the role of the media and the idea of creating a partnership involving media members in self-regulation. Panelists and commenters highlighted the role the media plays in disseminating deceptive weight-loss ads. A consumer who filed written comments emphasized the power of the media, and said individuals who see before-and-after pictures in magazines and on infomercials often believe the claims must be true if they are in print or on television.²³⁶ Another commenter, a social worker who specializes in eating disorders, noted that ads making “seductive promises of weight loss” appear in media everywhere.²³⁷

Panelists therefore recognized that a truly effective effort to stop deceptive weight-loss advertising would require the cooperation of media outlets. AHPA’s representative suggested that false weight-loss ads will persist as long as the media is willing to run them, and favored media filtering of these ads before they reach consumers.²³⁸ To aid in this process, he proposed that a partnership of interested academics, scientists, health care professionals, and organizations promoting the public interest – such as those persons and groups in attendance at the workshop – meet and produce a document to provide guidance not only to the industry, but also to the media.²³⁹ CRN supported the concept of a partnership among regulators, the industry, and the media that would realize a common goal of protecting consumers.²⁴⁰ The group viewed media involvement as a critical part of this partnership.²⁴¹ NAD likewise expressed interest in involving the media in any self-regulatory program, and said it hopes to see a cooperative system develop in which the media would consider more closely whether to run certain weight-loss ads.²⁴²

One possibility raised for launching a partnership with the media was to enlarge the role of the existing Partnership for Healthy Weight Management (Partnership). The Partnership is a coalition of representatives from science, academia, the health care profession, government, commercial enterprises, and organizations promoting the public interest.²⁴³ Its mission is to promote sound guidance to the general public on strategies for achieving and maintaining a healthy weight, and it engages in various consumer education efforts such as informing the public about the risks of being overweight and the benefits of weight loss, cautioning about the risks of unhealthy approaches to weight loss, and fostering realistic expectations about weight-loss products or programs.²⁴⁴ The Partnership’s panelist suggested expanding the group’s existing framework into more of a self-regulatory forum for weight-loss advertising.²⁴⁵ He also raised the possibilities of using the organization as a part of a certification program, or involving another entity, such as the International Food Information Council, in self-regulation.²⁴⁶

Overall, industry members supported the establishment of a joint partnership that would include advertisement screening by media groups. CRN also noted that the media can assist with consumer education by broadcasting messages, crafted by the industry and FTC, about effective weight loss and deceptive weight-loss ads.²⁴⁷ Efforts to involve the media in combating fraudulent weight-loss ads are ongoing, and the need to improve current media screening initiatives and promote consumer education was discussed in more detail during the media panel.

C. The Media Panel

The final panel of the workshop explored the potential roles the media could play to reduce the incidence of weight-loss fraud. The panel consisted of representatives from the three major media trade groups, two publishers, and academics in the fields of marketing, journalism ethics, and media law.²⁴⁸ As discussed above, there is recognition that law enforcement is not sufficient to address the prevalence of fraudulent weight-loss advertising;²⁴⁹ a multi-pronged approach is necessary, involving law enforcement, consumer education, industry self-regulation, **and** the media. The media panelists identified two roles for the media: (1) to educate the public on weight-loss fraud, and weight-loss issues generally; and (2) to reduce the dissemination of false weight-loss advertising. This section summarizes the panel discussion, with a particular focus on the current advertising clearance standards used by the media, the challenges identified by the media in screening advertising generally, and the ways the media could help combat weight-loss fraud. It also discusses how certain impediments faced by the media in reviewing advertisements could be overcome in the limited area of weight-loss.

1. Advertising Clearance Standards Vary Significantly Across the Cable, Newspaper, and Magazine Industries

The panelists primarily considered the advertising clearance practices of the cable, newspaper, and magazine industries.²⁵⁰ The panel observed that overall, clearance standards vary a great deal across media outlets.²⁵¹ For example, the Editor-in-Chief of *Good Housekeeping Magazine* stated that her magazine requires that advertisers substantiate all claims prior to publication, whereas, according to MPA, its members typically have adopted much less rigorous policies.²⁵² The media trade group representatives pointed out that cable systems, newspapers, and magazines reject advertisements for a wide array of reasons; often, it may hinge simply on whether the ad would be objectionable to the target audience.²⁵³ The NAA representative noted that credibility is critical to newspapers and that no one knowingly wants to run false or misleading ads.²⁵⁴ Most of the panel agreed that regardless of size, media outlets typically employ some type of basic ad review that, at a minimum, involves declining ads for reasons of taste or encouragement of illegal activities.²⁵⁵

a. Cable Industry²⁵⁶

At the workshop, the Cable Advertising Bureau's representative stated that in 1996 it issued voluntary advertising guidelines for its members, and it has periodically reviewed the guidelines since that time.²⁵⁷ The CAB's voluntary guidelines include a section that deals with weight-control advertisements.²⁵⁸ In surveying half of its membership, CAB found great variance in how its members cleared advertisements.²⁵⁹ Only 17% of the respondents reported using the CAB-distributed guidelines; the rest reported using non-CAB guidelines, which are typically of the members' own creation. Further, 75% of the CAB members surveyed claimed to have clearance departments. Because there is a wide range of programming on cable, according to CAB's representative, the type of advertising that is accepted for airing on any one channel depends highly on the audience.²⁶⁰ In its written comment, CAB explained that ad space on cable channels is sold through multiple levels by a wide network of companies, which compounds the complexity of ad review.²⁶¹ National and regional cable channels are principally owned by network operators; however, cable system companies – the entities that are responsible for technically delivering the programming to viewers – also often own their own channels, called “local origination channels.”²⁶² Moreover, CAB noted that cable channels not only sell advertising space directly to advertisers, but also typically reserve blocks of space that are sold locally by the cable system companies.²⁶³

b. Newspaper Industry²⁶⁴

During the workshop, the Newspaper Association of America representative reported that most newspapers adhere to fairly well-established guidelines for acceptability, declining ads for taste and obscenity.²⁶⁵ Also, some newspapers reject entire categories of ads, such as firearms, tobacco, alcoholic beverages, or adult material.²⁶⁶ NAA proffered that newspapers typically follow the generally accepted guideline that if there is a concern about an ad, a more senior person or committee will review it for placement.²⁶⁷ The NAA representative explained that a manager, or in the case of a larger newspaper, perhaps an advertising manager, would handle the review when there is a concern.²⁶⁸ According to NAA, other newspapers might refer the ad to an advertising review board or an advertising acceptability committee.²⁶⁹ By using this informal process, NAA said, newspapers are effective most times in identifying ads that are blatantly misleading, fraudulent, or illegal.²⁷⁰ According to NAA, however, newspapers typically conduct ad clearance on an ad-by-ad basis, and their practices cannot be encapsulated in a simple formula, and applied across the industry.²⁷¹

c. Magazine Industry²⁷²

Unlike the CAB, the Magazine Publishers of America has not formulated ad clearance guidelines for its members.²⁷³ The MPA representative stated that its members typically do not use formal review procedures.²⁷⁴ According to MPA, in some cases, for “philosophical” or “age-related” reasons, magazines might refuse to publish ads that promote certain product categories, for example, tobacco or alcoholic beverages.²⁷⁵ Further, MPA reported that some magazines, in exercising their discretion, also may decline mail-order ads that lack money-back guarantees.²⁷⁶ MPA emphasized, however, that employees of magazines do not “read” ads.²⁷⁷ During the session, two panelists – the Editor-in-Chief of *Good Housekeeping Magazine*, a major women’s magazine, and the Vice President of Standards at *New Hope Natural Media*, a publisher in the natural products industry – described advertising review for their publications. According to the representatives, each publication adheres to rigorous standards that require each claim to be substantiated,²⁷⁸ a process which *Good Housekeeping Magazine’s* representative believed was quite rare, based on her many years of experience in the magazine industry.²⁷⁹

2. Practical Impediments Faced by the Media in Reviewing Weight-Loss Ads

In light of current ad review practices, the media trade groups identified various practical reasons why it would be difficult for their members to screen weight-loss ads prior to dissemination. According to the trade groups, the chief obstacle for the media in conducting meaningful ad review is that they lack the requisite expertise to know whether a claim is deceptive.²⁸⁰ Most ads are handled by ad personnel – publishers, associate publishers, ad salespersons, and ad copy-readers – who are not equipped to properly evaluate ad claims.²⁸¹ Although publications like *Good Housekeeping Magazine* rely on the knowledge of their editorial departments to discern the credibility of ads, the NAA representative stated it is important to recognize that this is not the norm. For newspapers, he emphasized that the divide between the advertising department and the editorial department is sacrosanct; the editorial department does not get involved in the ad review process, and the ad department does not influence the editorial department.²⁸²

The media trade groups maintain that the costs to support a professional staff able to judge the accuracy of advertising would outpace the revenues of most media outlets, especially in the newspaper and magazine industries.²⁸³ In defense of this position, MPA and NAA in their joint comment highlighted the \$2.4 million a year expended by *Good Housekeeping Magazine* to operate its rigorous standards program.²⁸⁴ In CAB’s view, it is unreasonable to expect that the cable outlets could dedicate the same level of resources as the major broadcast networks to conducting advertising review.²⁸⁵

According to CAB's written comment, the three major television broadcast networks – ABC, NBC, and CBS – collect 10 times the ad revenues of the average cable network.²⁸⁶ The ERA concurred with the media group's observations, stating it was too burdensome for the media to be charged with the responsibility of pre-screening advertising.²⁸⁷

In addition, the media groups stated that the burden of screening is compounded by the sheer volume of ads to be reviewed and the tight deadlines that are an inherent part of the publishing and broadcasting businesses.²⁸⁸ CAB reported that the 2,500 cable systems represented by the CAB sell 2.7 billion units of advertising each year.²⁸⁹ Also, CAB stated that the 60 CAB-member channel networks²⁹⁰ that carry advertising sell more than 13 million commercial units annually, averaging 217,000 units per network.²⁹¹ According to CAB, the ads are constantly changing. Echoing CAB's observations, the NAA representative explained that the ads submitted to the newspapers for publication are not static, and the clearance process is new and different each day.²⁹² The NAA representative noted that, regardless of the clearance standards in place, newspapers – especially the daily publications – generally are required to make decisions in a short period of time, which makes for a very chaotic atmosphere in the ad departments.²⁹³ The Editor-in-Chief of *Good Housekeeping Magazine* conceded that, if she were on a 24-hour deadline, *Good Housekeeping's* standards program would be difficult to implement.²⁹⁴ Moreover, in its written comment, NAA also explained that in many cases, *pre-printed* ads are supplied by third-party ad brokers only hours before the paper goes to press, which serves to further amplify the time pressures.²⁹⁵

In the course of the discussion, the *Good Housekeeping Magazine* representative explained that, while overall her magazine's program was not "easy to administer," some ads, like ones that promise weight-loss of 10 pounds per week or that you can eat all the high calorie foods you want without diet or exercise and lose weight, require very little scrutiny before being rejected.²⁹⁶ In fact, according to her, these type of ads rarely are forwarded to her group by *Good Housekeeping's* ad department because the ad personnel know that they will not survive review.²⁹⁷ Also, the Vice President of Standards at *New Hope Natural Media* added that his publication has trained the ad sales representatives on what will and will not be accepted, so they are capable of immediately rejecting blatantly deceptive weight-loss ads.²⁹⁸ He said that the type of ads submitted to the standards department for review are ads that are "subtly misleading."²⁹⁹

3. Potential Roles for the Media

The panel widely recognized that there were roles for the media to play in the fight against weight-loss fraud. Many of the panelists suggested that the media are in a position to educate the

public. The NAA representative offered that the media could disseminate editorial material that addressed not only weight-loss fraud, but also the health crisis of obesity in the United States and weight-loss management in general.³⁰⁰ According to the MPA representative, in the past year more than 1300 articles on weight loss ran in magazines contained in the MPA database, which was consistent with what he viewed to be the historic role of the media.³⁰¹ *Good Housekeeping's* Editor-in-Chief further conveyed that it was important to inform the public because if consumers did not buy the fraudulent weight-loss products, advertisers would stop advertising them.³⁰² The CAB representative, in particular, supported the use of advertising to influence consumers in a positive way. He suggested running a public service announcement campaign on the subject of weight-loss fraud.³⁰³ In its comment, similar to CAB's proposal, ERA offered to work with its members and other industry groups, such as the Ad Council, to "facilitate the production and broadcast" of PSAs designed to educate consumers about weight loss.³⁰⁴

The Editor-in-Chief of *Good Housekeeping Magazine* advocated a dual approach to combat weight-loss fraud: educate consumers, and also educate the media on how to spot deceptive advertising.³⁰⁵ Recognizing a role for newspapers other than educating the public, the NAA comment stated that its members "are keenly interested in screening out material that may be harmful or offensive to their readers."³⁰⁶ Similarly, CAB indicated its interest in "identify[ing] possible means of reducing, if not completely precluding, the dissemination of claims that are unquestionably and egregiously false and misleading."³⁰⁷

One panelist said that in his view, from a practical perspective, the first step to solving the problem of weight-loss fraud is to equip the media with "knowledge."³⁰⁸ Along these lines, the NAA representative stated that it would be useful to furnish the media outlets with a one-page document of easily understood buzz words or alerts containing key phrases or numbers, or examples of problematic ad campaigns, which could be distributed to decision-makers at all levels in the newspapers.³⁰⁹ According to CAB's representative, it would be critical that such a guide or alert for the media be very specific, and not "vacuous," so that the cable outlets could act on it.³¹⁰ The NAA representative added that communicating this kind of information to its members would be one of its functions.³¹¹ Finally, in discussing a potential guide, the NAA representative cautioned that, while his group agrees that a guide would be helpful to newspapers in making the initial decisions about which weight-loss ads to accept and reject, he felt that the ultimate decision on what to publish and not to publish should reside with the publisher.³¹²

Despite the potential benefits of a guide to educate the media on deceptive weight-loss advertising, the media trade groups and the ERA voiced concern about media outlets' undertaking

efforts to screen weight-loss advertising. The MPA and NAA stated in their joint comment that even with such a guide, ad personnel would be forced to ascertain whether one of the scientifically infeasible weight-loss claims is being made in an ad, and if so, whether, read in context, the ad is in fact deceptive.³¹³ In its comment, ERA also expressed unease with the idea of the media screening for deceptive weight-loss ads because complex issues of ad interpretation would invariably arise, and the media would not be equipped to handle them.³¹⁴ According to the MPA representative and others, because of these difficulties, it is unlikely that publishers would even attempt to exercise judgment; they would address the problem by simply refusing to publish ads in the whole category of weight loss.³¹⁵

The trade groups and ERA expressed concern that, if saddled with the task of reviewing weight-loss advertising for accuracy, the media outlets most probably would react by rejecting all ads for weight-loss products and programs.³¹⁶ As a whole, the media groups, and ERA, argued that asking the media to screen for scientifically infeasible weight-loss claims would cause the suppression of non-misleading speech.³¹⁷ CAB and ERA in their written comments conveyed that this outcome not only would be costly to the media, but would be an unfair result for legitimate weight-loss advertisers and for consumers as well.³¹⁸

The Joint MPA/NAA Comment asserts that a media screening guide that listed prohibited claims would impose impermissible burdens on the media and chill protected speech.³¹⁹ This First Amendment issue was discussed at the workshop. Professor Fred Schauer indicated that the creation of a specific list of infeasible claims for the media to use in evaluating weight-loss advertising was a constitutionally permissible approach for the FTC to use to encourage the media to engage in self-regulation.³²⁰ Because the staff is merely encouraging the media to improve voluntary screening of scientifically infeasible weight-loss claims, issuance of media guidance does not raise First Amendment concerns.

III. Conclusion

A. Summary of the Workshop

The purpose of the workshop was threefold: (1) to solicit the scientific opinions of experts in the weight-loss field on the scientific feasibility of eight claims that appear in weight-loss ads; (2) to discuss how the weight-loss industry is addressing the problem of deceptive weight-loss advertising; and (3) to explore innovative ways for the media to assist in reducing the dissemination of deceptive

weight-loss advertising. Through the workshop, the staff gathered valuable information on the scientific feasibility of certain weight-loss claims, self-regulatory efforts in the weight-loss industry, and the clearance standards used by the cable, newspaper, and magazine industries, as well as the challenges faced by these media outlets to implement them.

At the workshop, the scientific experts generally expressed the view that the weight-loss claims under consideration were not scientifically feasible. Each of the panelists independently adjudged six of the eight weight-loss claims to be scientifically infeasible, with only one panelist expressing uncertainty regarding the other two claims. Accordingly, based on the workshop discussions, the written comments received before and after the workshop, the published scientific and medical literature, and its own investigative experience, the staff concludes that the claims set forth below are not scientifically feasible at the current time:

- Consumers who use the advertised product can lose two pounds or more per week (over four or more weeks) without reducing caloric intake and/or increasing their physical activity.
- Consumers who use the advertised product can lose substantial weight while still enjoying unlimited amounts of high calorie foods.
- The advertised product will cause permanent weight loss (even when the user stops using the product).
- The advertised product will cause substantial weight loss through the blockage of absorption of fat or calories.
- Consumers who use the advertised product (without medical supervision) can safely lose more than three pounds per week for a period of more than four weeks.
- Users can lose substantial weight through the use of the advertised product that is worn on the body or rubbed in to the skin.
- The advertised product will cause substantial weight loss for all users.
- Consumers who use the advertised product can lose weight only from those parts of the body where they wish to lose weight.³²¹

It is recognized that these messages can be stated in different ways and that to be useful for media screening purposes, the claims should be stated as simply as possible in conversational English. Accordingly, in industry and consumer education initiatives the staff may revise the wording of these claims and provide additional examples depending on the intended audience. Moreover, there was

considerable discussion at the workshop and in the written comments concerning the meaning of the word “substantial.” Nevertheless, workshop discussions regarding the scientific feasibility of most of these claims did not turn on the definition of “substantial.” Ultimately, in this context, the staff intends its common usage, *i.e.*, “a lot of weight.” Conservatively, any claim of one pound per week for more than four weeks (more than four pounds per month) is substantial, as well as total weight loss exceeding 15 pounds.

The panelists recognized that deceptive weight-loss advertising is a growing problem despite increased FTC law enforcement and consumer education efforts. To address the problem, the weight-loss industry expressed a willingness to strengthen self-regulation, including the development of more effective weight-loss advertising guidelines and the exploration of a larger role for the NAD. Many panelists also recognized that the media have a crucial part to play in reducing the dissemination of false weight-loss advertising. During the workshop, several panelists commented that the media are uniquely positioned to educate the public about weight-loss fraud, and to curb its exposure to the most egregious of weight-loss advertising through meaningful screening efforts. To this end, it appears that concise business guidance identifying scientifically infeasible weight-loss claims would significantly aid the media in screening out false weight-loss advertising. It would also assist the industry in developing effective self-regulatory guidelines for marketers of weight-loss products.

B. Weight-Loss Advertising Guidance for the Media

As noted above, the estimated cost of obesity exceeds \$100 billion per year and consumers are spending an estimated \$37.1 billion a year trying to prevent weight gain or to lose weight. In too many instances, however, the products being promoted for weight loss are worthless and the claims used to promote these products blatantly false. Money spent on worthless, over-hyped remedies distorts the market and injures consumers. History has taught us that law enforcement alone will not adequately address this issue; the question addressed here is whether there is a larger role for the media in this effort.

The media play a critical role in educating the public about weight-loss fraud and healthy weight-loss strategies, but their role need not be limited to education. In the past, consumer education alone has not proven sufficient to protect consumers from the pervasive counter-messages of easy weight-loss without diet or exercise. Significantly, the media have the power to reduce the amount of weight-loss fraud by curtailing the dissemination of blatantly false weight-loss advertising. Therefore, relying on input from the workshop and discussions with individual industry members, the staff is providing weight-loss advertising guidance, which will be released simultaneously with this report,

to aid media outlets in reviewing weight-loss advertising. This guidance includes seven of the eight claims identified in this report as scientifically infeasible,³²² and is intended to apply to nonprescription weight-loss products.³²³

The key to more effective media screening is to develop a common sense approach to the review of weight-loss ads that can be used by all media outlets – regardless of size, dissemination schedule, or expertise – to pick out with ease the worst of the deceptive weight-loss ads. Straightforward advertising guidance will equip the media outlets with the basic knowledge necessary to identify the most outrageous weight-loss claims – those that are simply too good to be true.

The media’s incorporation of the guidance into their clearance programs will require minimal resources. Most media already conduct some level of ad review to screen out advertisements that encourage illegal activity or that may be offensive to their viewers. Weight-loss advertising contributes only a small fraction of the total number of ads being disseminated at any one time.³²⁴ Moreover, the robust programs of media outlets such as *Good Housekeeping Magazine* and the major broadcast networks, while laudable, are not necessary to stop the obvious weight-loss fraud that was identified in the staff’s Weight-Loss Advertising Report. The vast majority of such ads can be identified and rejected by ad personnel without resort to resource-intensive evaluation procedures.³²⁵

The weight-loss advertising business guidance is designed to provide the media with an expert-supported basis for refusing to run advertisements that contain scientifically infeasible claims, without the need to investigate the scientific validity of each specific weight-loss claim.³²⁶ Use of the guide by the media in this manner does not obligate the media to investigate the accuracy of the wide array of advertising they disseminate to the public. A weight-loss advertising guide will aid media personnel to “eas[ily] notice and reject” ads that contain extreme weight-loss claims that are not scientifically feasible.³²⁷ The guide is intended to facilitate the same process with regard to obviously false weight-loss ads as is used by media outlets that voluntarily reject other types of ads based, not on the substance of the ad, but on a facial determination, such as whether the ad contains nudity or promotes an illegal or undesirable product.

Contrary to concerns raised in some comments, public and private encouragement that the media undertake voluntary programs to screen out the most outlandish weight-loss claims, in combination with the publication of advertising guidance that identifies scientifically infeasible claims, is unlikely to cause media outlets to respond by rejecting all weight-loss advertising. The more likely result is that the weight-loss product advertisers will eliminate obviously false claims from their ads so that they can continue to obtain broad dissemination of advertisements for their products. Although it is

still too early to tell with certainty, the staff believes that there already has been some movement in that direction.

In some instances, it may be difficult to determine whether an advertisement contains one of the identified claims.³²⁸ Perfection, however, is not required for the media to be successful in this venture to combat weight-loss fraud. Even by catching only the most obvious claims in question, the media could provide a valuable service. With merely a good faith effort to incorporate voluntarily the weight-loss advertising guidance as part of their clearance standards, the media outlets, as a whole, could reduce significantly the amount of false and deceptive weight-loss advertising that is disseminated to the public, and thereby reduce the incidence of weight-loss fraud.

Finally, it is important to understand that the seven claims included in the FTC staff's media guidance brochure do not constitute a complete listing of all unlawful, deceptive, or unsubstantiated claims that might be made by weight-loss advertisers. Although the FTC is seeking the assistance of the media and others in eliminating the claims included in the guidance, this action should not be construed as limiting the responsibility of advertisers to ensure that claims not on this list are truthful and not misleading.

IV. Recommendations

At the time of the FTC's Weight-Loss Advertising Report, false weight-loss advertising appeared to have reached unprecedented levels, resulting in unacceptable injury to consumers and legitimate businesses. Consumers lose money and confidence in the market. Legitimate businesses lose because the competitive environment is muddied, making it difficult, if not impossible, for consumers to select the best products available.

The dialogue between the FTC staff and the private sector since the release of the Weight-Loss Advertising Report has reaffirmed that we share a common goal of reducing current levels of false weight-loss advertising. Because we are beginning from a common goal, the FTC staff believes that substantial progress can be achieved through the following initiatives:

- First, there needs to be meaningful guidance to consumers, advertisers, and the media that identifies specific claims that are not scientifically feasible at the current time. The FTC staff has taken the first step toward this goal by preparing a list of obviously false weight-loss advertising claims that is being released simultaneously with this report.
- Second, the FTC will continue to encourage the media to implement viable media clearance standards based on the guidance set forth above. At the same time, the FTC

will encourage honest advertisers and their representatives to support this program. This initiative is intended to be voluntary, and the goal is to stop the dissemination of over-the-top, outrageous weight-loss advertising without adversely affecting truthful, nondeceptive advertisers. Accordingly, we will continue to work toward the development of third-party resources, such as assistance from the National Advertising Division of the BBB or other third parties, that media representatives can use, if necessary, to aid the process of media screening.

- Third, the FTC staff will continue to work with all interested public and private entities to develop self-regulatory weight-loss advertising guidelines that incorporate the guidance set forth above, and encourage the development of effective industry self-regulatory programs to implement such advertising guidelines. Work is currently underway through the Partnership for Healthy Weight Management and a number of trade associations, such as the American Herbal Products Association, to explore the development of weight-loss advertising guidelines that could facilitate the development of self-regulatory programs. In addition, the Electronic Retailers Association is developing a self-regulatory program that would involve a unit of the National Advertising Review Council in the review of electronic direct-response advertisements, including infomercials and short-form television ads. Although not limited to weight-loss advertisements, this program could provide a meaningful third-party review of weight-loss product infomercials and other direct-response weight-loss ads.
- Fourth, the FTC staff will work with private and public groups to develop consumer education programs. The FTC is working with the Electronic Retailing Association to develop a public service announcement aimed at consumers of weight-loss products.
- Fifth, the FTC staff will continue to monitor weight-loss advertising over the course of the next year to measure improvement. Based on the results of the continued monitoring, the staff will make further recommendations to the Commission as are necessary and appropriate, including recommendations that the Commission institute actions seeking preliminary and permanent injunctive and monetary equitable relief against advertisers who promote their products through false and deceptive claims.³²⁹

Endnotes

1. U.S. Department of Health and Human Services. The Surgeon General's call to action to prevent and decrease overweight and obesity. [Rockville, MD]: U.S. Department of Health and Human Services, Public Health Service, Office of the Surgeon General; [2001] at XIII, 10.
2. *Id.* at 10.
3. Serdula, M.K., *et al.*, *Prevalence of Attempting Weight Loss and Strategies for Controlling Weight*, 282 JAMA 1353-1358 (1999).
4. *Weight-Loss Advertising: An Analysis of Current Trends, A Report of the Staff of the Federal Trade Commission* (Sept. 2002) ("Weight-Loss Advertising Report").
5. *The U.S. Weight Loss & Diet Control Market* (7th ed. October 2002) Marketdata Enterprises, Inc. at 6. According to Marketdata, the total U.S. weight-loss market for 2001 is estimated to be \$37.1 billion and growing at a rate of 6 to 7 percent a year.
6. The Partnership for Healthy Weight Management is a coalition of representatives from science, academia, the health care profession, government, commercial enterprises, and organizations promoting the public interest. Its mission is to promote sound guidance to the general public on strategies for achieving and maintaining a healthy weight. It engages in various consumer education efforts, and has published guidelines for providers of weight-loss products and services. For more information on the Partnership, see <http://www.consumer.gov/weightloss/index.htm>.
7. Weight-Loss Advertising Report (cited in note 4).
8. *Id.* at x, 30. This determination was made based on a facial examination of the ads. The remaining 45% of the ads also may have contained false or deceptive claims, but additional investigation would have been required to assess the accuracy of these ads.
9. *Id.* at 31.
10. *FTC Announces Public Workshop to Discuss the Advertising of Weight-Loss Products* (Sept. 17, 2002), available at <http://www.ftc.gov/opa/2002/09/weightloss.htm>.
11. The workshop was entitled *Deception in Weight Loss Advertising: A Workshop*. Information about the workshop, including the agenda, transcript, panelist bios, and public comments, can be found at <http://www.ftc.gov/bcp/workshops/weightloss>.
12. Notice of Public Workshop, 67 Fed. Reg. 59,289 (Sept. 20, 2002), available at <http://www.ftc.gov/05/2002/09/weightlossfrn.htm>.
13. The FTC staff selected the eight claims based on representations challenged in past FTC investigations. Most of the examples used at the workshop and in this report come from ads reviewed for the Weight-Loss Advertising Report.
14. The panelists were Anthony Almada, B.Sc., M.Sc., of IMAGINutrition, Inc./MetaResponse Sciences; George Blackburn, M.D., Ph.D., of Harvard Medical School; Denise Bruner, M.D., of the American Society of Bariatric Physicians; Harry Greene, M.D., of Slim Fast Foods Company and the Partnership for Healthy Weight Management; Steven Heymsfield, M.D., of St. Luke's-Roosevelt Hospital Center and Columbia University College of Physicians and Surgeons; Van Hubbard, M.D., Ph.D., of the National Institutes of Health; Judith Stern, S.M., Sc.D., of

the University of California-Davis; Lawrence Stifler, Ph.D., of Health Management Resources; Thomas Wadden, Ph.D., of the University of Pennsylvania School of Medicine; and Susan Yanovski, M.D., of the National Institutes of Health. See Appendix A for biographical sketches of the panelists. Unless otherwise indicated, the opinions expressed by the panelists reflect their personal views, and do not necessarily reflect the views or official policy of the organizations they represent.

15. Medically unsupervised very low calorie diets, however, were discussed in connection with the consideration of the claim that users can safely lose three pounds per week or more over extended periods of time because the panelists did not view weight loss in the range of three pounds per week to be feasible without a substantial restriction on caloric intake. The panelists expressed the view that a medically unsupervised diet low enough in calories to cause three pounds of weight loss per week over an extended period of time cannot be considered safe. See *Deception in Weight Loss Advertising: A Workshop* (Nov. 19, 2002), Transcript at 99-100, 102-04, 107-08, 110-11. References to the workshop transcript in this report appear as “Tr.” followed by the page number and name of the speaker, if applicable. The workshop transcript is available online at <http://www.ftc.gov/bcp/workshops/weightloss/transcripts/transcript-full.pdf>.
16. Nevertheless, a claim that weight loss would be permanent after discontinuing use of the product or service would be questionable for prescription drugs, as well as for the products considered at the workshop.
17. Although this report concludes that this claim is not scientifically feasible when made in the context of an ad promising substantial weight loss, it has not been included in the FTC staff’s media guidance brochure (guidance), which is being released simultaneously with this report, because the claim does not appear to be widespread. Other claims, most notably, the claim that users can lose substantial weight loss without dieting or increasing exercise, have been modified slightly in the guidance to provide a clear, unequivocal standard.
18. In its supplemental comment, the Electronic Retailing Association (“ERA”) asserts that the scientific panel’s analysis should not be taken as reliable, citing, among other things, the limited representation of industry on the panel. See ERA, “Supplementary Comments of the Electronic Retailing Association to the Federal Trade Commission’s Workshop and Staff Report on Advertising of Weight-Loss Products” (“ERA Comment II”), Feb. 3, 2003, at 2-4. With regard to this objection, the staff believes that the attached biographical sketches demonstrate that all of the panelists had extensive expert credentials. Moreover, the FTC’s Federal Register Notice requested that persons interested in appearing on any of the panels contact the FTC staff. No scientist representing the weight-loss or dietary supplement industry who requested to sit on the science panel was rejected. Finally, no dietary supplement or weight-loss industry representatives submitted post-workshop comments challenging the panel members’ analyses. Public comments are available online at <http://www.ftc.gov/bcp/workshops/weightloss/comments/index.htm>.
19. Tr. at 17-19. If a claim is not biologically plausible, it will not be scientifically feasible; a biologically plausible claim, however, could be infeasible because of the lack of knowledge or technology.
20. Panelist Dr. Steven Heymsfield presented the following well-established general principles of weight control. The difference between energy intake and energy output, *i.e.*, energy balance, is the ultimate determinant of weight loss and weight change. Energy intake consists of consumed

calories. Energy output occurs both through physical activity (approximately one-third of expended calories) and basal metabolism (approximately two-thirds of expended calories). According to Dr. Heymsfield, there are four ways to lose weight: (1) reduce food intake; (2) block or limit the absorption of food (malabsorption); (3) increase energy expenditure (by either increasing physical activity or increasing resting metabolic rate (amount of heat the body produces)); and (4) re-partition existing energy, *i.e.*, change the body's proportion of fat to lean. This model can be used to analyze the validity of most of the claims discussed below. *See* Tr. at 20-25.

21. Tr. at 13-14, 17-19.
22. *See, e.g.*, Tr. at 35-36, 58-59.
23. *See, e.g.*, Tr. at 80-81, 97-98.
24. In their joint comment, the Magazine Publishers of America (“MPA”) and the Newspaper Association of America (“NAA”) assert that this is a different claim than “lose substantial weight without reducing caloric intake and/or increasing physical activity.” MPA/NAA, “Comments of the Magazine Publishers of America, Inc. and the Newspaper Association of America” (“Joint MPA/NAA Comment”), Feb. 3, 2003, at A-4. Rather, according to the MPA/NAA comments, the example given is a “hyper-specific weight loss claim pursuant to a universal timetable.” On the contrary, the average consumer would consider 28 pounds in four weeks to be substantial weight loss and statements such as “eat all your favorite foods” and the “pill does all the work” to imply that dieting and increased exercise are not required. The Joint MPA/NAA Comment addresses each of the eight claims. The comments on each claim will be considered below.
25. The four measurements commonly used in weight loss ads are pounds, dress size, inches, and amount of body fat, any one of which can be used to convey the message of substantial weight loss. Additional examples of this claim include:
 - I lost 30 pounds in 30 days even though I ate all my favorite foods.
 - This product is so powerful, so effective, so relentless in its attack on fatty deposits that there is virtually no need to diet. ...Lose 36 pounds in 5 weeks; 60 pounds in 43 days; 42 pounds in 3 weeks; 12 pounds in 15 days.
 - I lost 15 pounds in 30 days without having to change my eating habits or lifestyle in any way. *See* results fast without the back-breaking exercise!
 - Go from a size 12 to a size 6; lose inches QUICKLY and do absolutely nothing but take this pill.
26. Tr. at 83-84. Mr. Almada agreed that it was not scientifically feasible for any of these ingredients to produce weight loss in the range of 28 pounds in four weeks. Tr. at 84.
27. Tr. at 85.
28. Tr. at 87. Re-partitioning refers to a change in the body's proportion of fat to lean. *See* note 20.
29. Tr. at 88.
30. Tr. at 89.
31. Tr. at 90.

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32. *Id.*
 33. Tr. at 96.
 34. Tr. at 96-97.
 35. *Id.*
 36. Tr. at 97-98.
 37. Joint MPA/NAA Comment (cited in note 24) at A-4 to A-5. The record of the workshop contains several discussions of the meaning of substantial weight loss. In each case, the majority of the experts did not believe that a precise definition of the term substantial weight loss was required, because the amount of weight that could possibly be lost through the purported mechanisms was, at best, trivial. *See, e.g.*, Tr. at 67-68, 90.
 38. The *Super Formula* product contained chromium picolinate, hydroxycitric acid, chitin, and glucomannan.
 39. *FTC v. SlimAmerica, Inc.*, 77 F. Supp. 2d 1263 (S.D. Fla. 1999). *See also FTC v. Slim Down Solution, LLC*, No. 03-80051-CIV-PAINE (S.D. Fla. filed Jan. 24, 2003); *FTC v. Mark Nutritionals, Inc.*, No. SA02CA1151EP (W.D. Tex. filed Dec. 5, 2002); *FTC v. No. 9068-8425 Quebec, Inc. d/b/a Bio Lab*, No. 1:02:CV-1128 (N.D.N.Y. July 28, 2003) (stipulated final judgment); *National Dietary Research*, 120 F.T.C. 893 (1995) (consent order); *Body Wise Int'l*, 120 F.T.C. 704 (1995) (consent order); *Taleigh Corp.*, 119 F.T.C. 835 (1995) (consent order); *FTC v. Shell*, No. 90 0120 (Kx) (C.D. Cal. Apr. 8, 1991) (stipulated permanent injunction).
 40. 77 F. Supp. 2d at 1273.
 41. One expert on the panel referred to a 1984 study of glucomannan that reported weight loss of 5.5 pounds over 8 weeks without any changes in diet or physical activity. Walsh, D.E., *et al.*, *Effect of Glucomannan on Obese Patients: A Clinical Study*, 8 International Journal of Obesity 289-93 (1984). In this study, patients were instructed not to deviate from their previously established eating and exercise patterns. This study is not particularly persuasive given the small number of subjects in the treatment group (10) and the fact that subjects did not maintain appropriate food diaries. There is no way to be sure that subjects did not change eating patterns. In fact, one of glucomannan's purported mechanisms of action is as a bulking agent, and the authors note it "added bulk in the stomach just before each meal, [which] may decrease the appetite and [cause subjects] to eat less at each meal." *Id.* at 292.
 42. *See generally* Allison, D.B., *et al.*, *Alternative Treatments for Weight Loss: A Critical Review*, 41 Critical Reviews in Food Science and Nutrition 1, 2-3, 18-20 (2001). One common problem in studies cited to support claims of weight loss without reducing caloric intake is the lack of any monitoring of caloric intake in those studies. *See, e.g.*, Walsh (cited in note 41).
 43. *See* Dulloo, A.G. *et al.*, *Efficacy of a green tea extract rich in catechin polyphenols and caffeine in increasing 24-h energy expenditure and fat oxidation in humans*, 70 Am J Clin Nutr 1040-45 (1999) (comparing 24 hour energy expenditure in subjects given either caffeine, green tea extract (including caffeine), or placebo); *see also Green Tea for Weight Loss?*, Tufts Univ. Health & Nutrition Letter, June 2003, at 3, quoting Jeffrey Blumberg, PhD: "It can't be concluded that [the] small increase in metabolism" reported in studies on green tea, "that could easily be undone by eating a single cookie or a handful of chips," could lead to weight loss.

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44. A recently released analysis indicates that there is scientific support that supplements containing ephedra and caffeine-containing herbs or ephedrine plus caffeine may cause weight loss of about ½ pound per week over four to six months. *Evidence Report/Technology Assessment, Number 76, Ephedra and Ephedrine for Weight Loss and Athletic Performance Enhancement: Clinical Efficacy and Side Effects*, U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality, Feb. 28, 2003, at 219. It is not entirely clear how much of this modest effect is due to increased metabolism and how much is due to appetite suppression, but it has been estimated that at least half of the effect is due to appetite suppression. See Tr. at 90 (Anthony Almada and Dr. Steven Heymsfield). Some ephedrine studies have reported a 10% increase in metabolic rate. See Greenway, F.L., *The safety and efficacy of pharmaceutical and herbal caffeine and ephedrine use as a weight loss agent*, *The International Association of the Study of Obesity*, 2 *Obesity Reviews* 3:199-211, 202 (2001). In any event, the effect, if any, without also reducing caloric intake would appear to be quite limited. For example, one ephedrine and caffeine study found that 75 percent of the weight loss was explained by anorexia and 25 percent by increased thermogenesis. See *id.* at 204.
45. American men and women consume, on average, about 2800 and 1800 calories per day, respectively, but there are large variations based on body size and other factors. Kathleen Melanson and Johanna Dwyer, *Popular Diets for Treatment of Overweight and Obesity*, in *Handbook of Obesity Treatment* 250 (Thomas A. Wadden and Albert J. Stunkard eds., New York: The Guilford Press, 2002).
46. The specification of two pounds in this claim is conservative. The scientific literature does contain reports of studies that claim to have tested certain ingredients without diet or exercise. Two pounds of weight loss per week over a period of four weeks (eight pounds per month), however, significantly exceeds the results reported in these studies and would still include the most obviously exaggerated claims. It also would take into account temporary fluid loss during the initial week to 10 days. Accordingly, this modified version of the claim is included in the FTC staff’s media guidance brochure. It should be emphasized, however, that ads that claim weight loss of less than two pounds per week without dieting or increasing exercise may still be false or unsubstantiated. The two pounds per week level is used here solely for the purpose of establishing a performance limit that is beyond reasonable scientific debate.
47. Additional examples of this claim include:
- I can have my bacon, sausage and grits and still lose weight.
 - This breakthrough ingredient has patients losing one full pound every 8 hours, 3 pounds more each day and all without counting calories, without missing a single meal and without giving up those delicious, mouth watering foods they love the most.
 - My “formula for living” lets you eat: Hamburgers, Hotdogs, Fries, Steak, Ice Cream, Sausage, Bacon, Eggs, Cheeses! And STILL LOSE WEIGHT!!”
 - I lost 9 pounds during my first week eating just as I always do, going to parties, even eating gobs of vacation goodies including my favorite: ice cream. Four weeks later and I’ve lost another 27 pounds.
 - Eat any mouth watering food you want and still blast away dress sizes and belt notches lightning fast!
48. Tr. at 46.

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49. Tr. at 47.
50. Tr. at 48.
51. Tr. at 50.
52. Tr. at 48.
53. Tr. at 51.
54. Joint MPA/NAA Comment (cited in note 24) at A-2. The Joint MPA/NAA Comment also asserts that research on the Atkins diet proves that a person can eat an unlimited number of calories and still lose weight. *Id.* The Atkins diet is not one of the covered products, nor are any plans that involve changing the way consumers eat. An analysis of the scientific research underlying the Atkins and other diets is beyond the scope of this report.
55. *Porter & Dietsch, Inc.*, 90 F.T.C. 770, 873 (1977), *aff'd*, 605 F.2d 294 (7th Cir. 1979). In *Porter & Dietsch*, the Commission held that it is deceptive to represent, directly or by implication, that use of an appetite suppressant enables users to lose body weight or fat without dieting or restricting accustomed caloric intake. 90 F.T.C. at 864-65, 866-67. The Commission found that claims that users could lose weight without restricting caloric intake and while continuing to eat foods of their choice, were “false, misleading and deceptive.” *Id.* at 866-67. The Commission further stated, “Where dieting is required, there is simply no substitute for clear and conspicuous disclosure that dieting is required.” *Id.* at 865. In *Porter & Dietsch*, one of the respondent’s ads that the Commission found deceptive contained the headline, “EAT WHAT YOU WANT – AND SLIM DOWN.”
56. For example, “takes away the craving so you do not want to eat.”
57. *Porter & Dietsch*, 90 F.T.C. at 873; *see also FTC v. Enforma Natural Prods.*, No. 00-4376JSL (Cwx) (C.D. Cal. Apr. 25, 2000) (stipulated final judgment); *FTC v. USA Pharmacal Sales, Inc.*, No. 8:03-CV-1366-T-23-EAJ (M.D. Fla. July 2, 2003) (stipulated final judgment); *FTC v. Health Labs. of N. America*, No. 03-1457 (D.D.C. July 17, 2003) (stipulated final judgment).
58. Additional examples of this claim include:
- Thousands of dieters are already using it and losing weight faster than they have before... and keeping the weight off.
 - For 15 years, Mary yo-yo dieted without success, fed up and desperate she discovered a new miracle product to lose weight easily and permanently.
 - The amazing “Fat-Sponge In a Pill” that lets you eat more, weigh less and finally... yes, finally... slim down for good for the rest of your life.
 - Tired of yo-yo diets without success, this miracle product lets you lose the weight easily and permanently.
 - It can help you quickly lose weight, and keep it from returning.
59. Tr. at 37-38.
60. Tr. at 39.
61. Tr. at 39-40.

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62. Tr. at 41-42.
 63. Tr. at 42-43.
 64. Tr. at 45.
 65. Joint MPA/NAA Comment (cited in note 24) at A-2. Although Xenical is a prescription drug and not a covered product as set out above, the discussion of the weight-loss performance of Xenical is relevant to the issue of scientific feasibility.
 66. Tr. at 44.
 67. Tr. at 45.
 68. Joint MPA/NAA Comment (cited in note 24) at A-1 to A-2.
 69. In fact, very few of the advertisements reviewed for the Weight-Loss Advertising Report that made a permanent weight-loss claim even addressed the issue of continued use of the product.
 70. *See, e.g., FTC v. No. 9068-8425 Quebec, Inc. d/b/a Bio Lab*, No. 1:02:CV-1128 (N.D.N.Y. July 28, 2003) (stipulated final judgment); *FTC v. USA Pharmacal Sales, Inc.*, No. 8:03-CV-1366-T-23-EAJ (M.D. Fla. July 2, 2003) (stipulated final judgment).
 71. *Methods for Voluntary Weight Loss and Control*, NIH Technol. Assess. Conf. Statement Online 1992 Mar. 30-Apr. 1; 10.
 72. Thomas, P.R., ed., *Weighing the Options: Criteria for Evaluating Weight-Management Programs 1* (National Academy Press 1995).
 73. The FTC has challenged weight loss maintenance/permanent weight loss claims as deceptive in a number of cases, including most recently, *FTC v. USA Pharmacal Sales, Inc.*, No. 8:03-CV-1366-T-23-EAJ (M.D. Fla. July 2, 2003) (stipulated final judgment), *FTC v. Mark Nutritionals, Inc.*, No. SA02CA1151EP (W.D. Tex. filed Dec. 5, 2002), and *FTC v. No. 9068-8425 Quebec, Inc. d/b/a Bio Lab*, No. 1:02:CV-1128 (N.D.N.Y. July 28, 2003) (stipulated final judgment).
 74. It may not be possible to determine without further investigation whether a more explicit claim that users can maintain weight loss as long as they continue using a particular product is false or unsubstantiated. Therefore, this type of claim cannot be rejected on its face as not being scientifically feasible. Nonetheless, it could still be deceptive depending on the substantiation for the specific product.
 75. Additional examples of this claim include:
 - Brindall berries cause very rapid and substantial weight loss by reducing fat absorption by 76%.
 - Super Fat Fighting Formula Guarantees Rapid Weight Loss. Shortly after ingesting small amounts of the component, it dissolves into a gel that absorbs and surrounds excess fat and calories, preventing them from forming body fat.
 - *This product blocks fat before your body absorbs it; the pounds will melt away effortlessly.*
 - Reduce fat absorption by 76% and lose substantial weight rapidly.
 - [XXXX] is an “all natural ingredient” designed to attract and absorb excess calories and transport them out of your system. Watch the weight come off your body.

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76. Tr. at 60.
 77. Tr. at 62. Dr. Wadden reached the same conclusion. Tr. at 65-66.
 78. Tr. at 61. *See* Gades, M.D. and Stern, J.S., *Chitosan Supplementation and Fecal Fat Excretion in Men*, 11 *Obesity Research* 683-88 (May 2003); Gades, M.D. and Stern, J.S., *Chitosan supplementation does not affect fat absorption in healthy males fed a high-fat diet, a pilot study*, 26 *International Journal of Obesity* 119-133 (2002).
 79. *See* Tr. at 63-68.
 80. *See* Tr. at 66-68.
 81. Tr. at 68.
 82. Tr. at 71.
 83. Joint MPA/NAA Comment (cited in note 24) at A-3 to A-4.
 84. Tr. at 68.
 85. *Id.*
 86. Even prescription drugs do not produce such dramatic results. For example, orlistat (Xenical™) is an extensively studied pharmacological agent that produces malabsorption of approximately one-third of dietary fat in a meal. Louis J. Aronne, *Treatment of Obesity in the Primary Care Setting*, in *Handbook of Obesity Treatment* 390 (Thomas A. Wadden and Albert J. Stunkard eds., New York: The Guilford Press, 2002); *see also* George A. Bray, *Drug Treatment of Obesity*, in *Handbook of Obesity Treatment* 327 (Thomas A. Wadden and Albert J. Stunkard eds., New York: The Guilford Press, 2002) (discussion of orlistat response to treatment rates). Beyond this amount, users experience significant gastrointestinal disturbance, including loose stool and diarrhea. *See* Bray at 328-29; Aronne at 390. On a 60 grams of fat per day diet, approximately 180 calories per day would not be absorbed, resulting in weight loss of approximately one-third of a pound per week. By itself, this amount of weight loss would not be substantial, as that term is used here. *See* Tr. at 60-61, 62, 66, and 67. The evidence of significant weight loss achieved through agents such as orlistat is based on use of the agent in combination with a restricted calorie diet. For example, used in combination with a low calorie diet, orlistat has been reported to result in an 8% weight loss after a year compared with 4% in a control group. The control group was also on a low calorie diet. *See* Aronne at 390. Thus, the weight loss is not attributable to blocking the absorption of fat alone.
 87. Tr. at 60 (Dr. Judith Stern). Seven thousand calories represents approximately 750 grams of fat daily. On a 2,500 calorie per day diet consisting of 40% fat, a person would consume only about 110 grams of fat.
 88. *See, e.g., FTC v. Enforma Natural Prods., Inc.*, No. 00-4376JSL (Cwx) (C.D. Cal. Apr. 25, 2000) (stipulated final judgment) (\$10 million in consumer redress); *FTC v. Slim Down Solution, LLC*, No. 03-80051-CIV-PAINE (S.D. Fla. filed Jan. 24, 2003); *FTC v. KCD Inc.*, 123 F.T.C. 1535 (1997) (consent order).
 89. *See* Gades and Stern (cited in note 78); Pittler, M.H., *et al.*, *Randomized, double-blind trial of chitosan for body weight reduction*, 53 *European Journal of Clinical Nutrition*, 379-81 (1999); Wuolijoki, E., *et al.*, *Decrease in Serum LDL Cholesterol with Microcrystalline Chitosan*, 21 *Methods Find. Exp. Clin. Pharmacol.*, 357-61 (1999); and Ho, S.C., *et al.*, *In*

the Absence of Dietary Surveillance, Chitosan does not Reduce Plasma Lipids or Obesity in Hypercholesterolaemic Obese Asian Subjects, 42 Singapore Med J, 1: 6-10 (2001).

90. Tr. at 99.
91. Tr. at 99-100.
92. Tr. at 101.
93. Tr. at 102-05.
94. Tr. at 106.
95. Tr. at 107-08.
96. Tr. at 108-10.
97. Tr. at 109.
98. Tr. at 110-11. Consistent with the expert panel's conclusion, the U.S. Dietary Guidelines for Americans state that "[l]oss of ½ to 2 pounds per week is usually safe." U.S. Dept. of Agriculture and U.S. Dept. of Health and Human Services, U.S. Dietary Guidelines for Americans, 2000, at 9.
99. Joint MPA/NAA Comment (cited in note 24) at A-6.
100. Tr. at 106-08.
101. *Weighing the Options* at 115-17 (cited in note 72); Edward W. Gregg and David F. Williamson, *The Relationship of Intentional Weight Loss to Disease Incidence and Mortality*, in *Handbook of Obesity Treatment* 126-27 (Thomas A. Wadden and Albert J. Stunkard eds., New York: The Guilford Press, 2002). The indication of four weeks is made here to distinguish short term, e.g., weekend, crash diets.
102. *Weighing the Options* at 115 (cited in note 72).
103. See note 101.
104. In this case, a covered product, such as a dietary supplement, could be sold as part of a "program" that included a very low calorie diet.
105. Wadden, T.A., *et al.*, "The Cambridge Diet: More Mayhem?" 250 JAMA 2833 (1983).
106. Tr. at 74.
107. No transdermal diet patch has been approved by the U.S. Food and Drug Administration for weight loss or weight control. Pursuant to Sections 201(g), 201(p), 301(d) and 505 of the federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 321(g), 321(p), 331(d) and 355, introduction of such an article into interstate commerce is prohibited by law.
108. Tr. at 78-79. These issues include bioavailability and dose levels, *i.e.*, whether a sufficient dose of an effective ingredient can be delivered transdermally.
109. Tr. at 75-76. See also Allison (cited in note 42) at 2-3 ("methodologically rigorous studies tend to find no effect").
110. Tr. at 81.

111. *Id.*

112. *Kave Elahie/M.E.K. Int'l*, 124 F.T.C. 407 (1997) (consent order; aminophylline cream); *2943174 Canada, Inc.*, 123 F.T.C. 1465 (1997) (consent order; transdermal diet patch); *Guildwood Direct Ltd.*, 123 F.T.C. 1558 (1997) (consent order; slimming insoles); *Bodywell, Inc.*, 123 F.T.C. 1577 (1997) (consent order; slimming insoles); *Original Mktg., Inc.*, 120 F.T.C. 278 (1995) (consent order; acupressure device); *European Body Concepts, Inc.*, 119 F.T.C. 947 (1995) (consent order; body wrap); *Ninzu, Inc.*, 119 F.T.C. 421 (1995) (consent order; acupressure device); *Spanish Telemktg. Indus., Inc.*, 114 F.T.C. 754 (1991) (consent order; cream and belt); *Richard Crew*, 114 F.T.C. 230 (1991) (consent order; transdermal patch); *Robert Francis*, 114 F.T.C. 24 (1991) (consent order; transdermal patch).

113. *See* note 109; Tr. at 77.

114. *See* Allison (cited in note 42) at 18.

115. *See* Greenway, F.L., *et al.*, *Topical Fat Reduction*, 3 Obesity Research 4:561S-568S (1995); Greenway, F.L. and Bray, G.A., *Regional fat loss from the thigh in obese women after adrenergic modulation*, 9 Clin. Ther., 6: 663-669 (1987).

116. Tr. at 79 (Dr. George Blackburn).

117. *See* note 107.

118. Additional examples of this claim include:

- Everyone in our study lost substantial weight. Failure is impossible.
- Melt away ugly body fat. The product targets fat and eliminates it, regardless of body type and size.

119. Tr. at 28.

120. Tr. at 29.

121. *Id.*

122. Tr. at 30.

123. Tr. at 30-31.

124. Tr. at 31.

125. Tr. at 32.

126. *Id.*

127. Tr. at 32-33.

128. Tr. at 33.

129. Tr. at 33-35.

130. Tr. at 35-36.

131. Joint MPA/NAA Comment (cited in note 24) at A-1.

132. *See, e.g.*, Tr. at 31 (Dr. Lawrence Stifler) (discussion of restricted caloric diet).

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133. As discussed earlier, FTC case law is well established that where a product requires a restricted caloric intake to be effective, that fact must be clearly and prominently disclosed in the advertising for the product. *Porter & Dietsch*, 90 F.T.C. at 865.
134. Tr. at 29-30, 35-36 (Anthony Almada).
135. For a discussion of factors contributing to overweight and obesity, see R. Arlen Price, *Genetic and Common Obesities: Background, Current Status, Strategies, and Future Prospects*, and Katherine Battle Horgen and Kelly D. Brownell, *Confronting the Toxic Environment: Environmental and Public Health Actions in a World Crisis*, in *Handbook of Obesity Treatment* 73-106 (Thomas A. Wadden and Albert J. Stunkard eds., New York: The Guilford Press, 2002).
136. Tr. at 29-31.
137. Tr. at 28 (Dr. Steven Heymsfield); Tr. at 29 (Dr. George Blackburn); see also Bray (cited in note 86) at 327 (discussion of orlistat response to treatment rates); Aronne (cited in note 86) at 389.
138. Although this report concludes that this claim is not scientifically feasible when made in the context of an ad promising substantial weight loss, it has not been included in the guidance because the claim does not appear to be widespread.
139. Tr. at 52-53.
140. See studies cited in note 115.
141. Tr. at 54.
142. Tr. at 54-55.
143. Tr. at 56.
144. See Tr. at 56-59.
145. Tr. at 58.
146. Tr. at 59.
147. See *id.*
148. Joint MPA/NAA Comment (cited in note 24) at A-3.
149. Tr. 58-59.
150. See Greenway, *Topical Fat Reduction* and Greenway and Bray (cited in note 115).
151. For example, in the largest of these studies, the difference between the treatment and control condition at the upper thigh measurement was $0.78 \pm .89$ cm over 6 weeks. See Greenway, *Topical Fat Reduction* (cited in note 115) at 567S.
152. Greenway, *Topical Fat Reduction* (cited in note 115) at 567S.
153. See Allison (cited in note 42) at 18.
154. This claim essentially requires three distinct elements: (1) that the product will cause substantial weight loss; (2) that weight loss will occur in specific parts of the body; and (3) that there will be no weight loss in certain other parts of the body. Thus, an advertisement that claimed only that users could reduce the size of their hips or waist would not be included in this claim. *But*
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see, e.g., Boozer, et al., An herbal supplement containing Ma Huang-Guarana for weight loss: a randomized, double-blind trial, 25 International Journal of Obesity 316-324 (2001) (study reported statistically significant weight loss in hips and waist). This distinction could be confusing to persons attempting to apply the guidance to specific advertisements.

155. The panelists were Brad Bearnsen, Esq., of ICON Health & Fitness; John Cordaro of the Council for Responsible Nutrition (“CRN”); Harry Greene, M.D., of the Partnership for Healthy Weight Management and Slim Fast Foods Company (representing the Partnership for Healthy Weight Management); Andrea Levine, Esq., of the National Advertising Division of the Council of Better Business Bureaus (“NAD”); Michael McGuffin of the American Herbal Products Association (“AHPA”); Lisa Myers of the Electronic Retailing Association (“ERA”); David Seckman of the National Nutritional Foods Association (“NNFA”); and Lewis Shender, Esq., of Jenny Craig. *See* Appendix A for biographical sketches of the panelists.
156. NNFA, “Advertising of Weight Loss Products Workshop–Comment” (“NNFA Comment”), Jan. 29, 2003 at 1. Established in 1936, the National Nutritional Foods Association is the oldest and largest non-profit trade group for the natural products industry. Its membership includes over 4,000 retailers, manufacturers, wholesalers, and distributors of natural products, including foods, dietary supplements, and health and beauty aids. Members range from small health food stores to large dietary supplement makers. *Id.*
157. *Id.*
158. *See* Tr. at 134-36 (Lisa Myers). The Electronic Retailing Association is a trade group for the electronic retailing industry. It has over 450 members, including advertising agencies, direct response marketers, telemarketers, Internet and brick and mortar retailers, fulfillment service providers, and television shopping channels such as HSN and QVC. ERA Comment II (cited in note 18) at 1.
159. Tr. at 135 (Lisa Myers).
160. *Id.* (referring to clips from the infomercials for Enforma Natural Products and Pound-A-Patch). The companies behind both infomercials were one-time ERA members. *Id.* at 120.
161. *Id.* at 148.
162. Tr. at 136 (John Cordaro). The Council for Responsible Nutrition is a trade association of approximately 85 manufacturers of dietary supplements, some of whom manufacture and market weight-loss products. *Id.* at 118. Its panelist likened false and deceptive weight-loss ads to incredible spam messages that promise recipients millions of dollars if they will just send a few thousand to help “break it loose.” *Id.* at 136.
163. *See* Tr. at 121-23.
164. *See* Tr. at 122-23.
165. Tr. at 121 (Lewis Shender).
166. Tr. at 122 (Brad Bearnsen).
167. Tr. at 118 (John Cordaro).

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168. Tr. at 127 (Michael McGuffin). The American Herbal Products Association is a trade association that represents about 200 companies, primarily marketers of herbal dietary supplements, including some products promoted for weight loss. *Id.* at 119.
169. *See* Tr. at 120 (Lisa Myers); ERA, “Comments of the Electronic Retailing Association to the Federal Trade Commission’s Workshop and Staff Report on Advertising of Weight Loss Products” (“ERA Comment I”), Oct. 31, 2002, at 2.
170. NNFA Comment (cited in note 156) at 1.
171. *See* Tr. at 170-73.
172. Tr. at 172-73 (Michael McGuffin).
173. Tr. at 173 (David Seckman, Lewis Shender); *see also* Tr. at 170-71 (Brad Bearnson) (supporting FTC’s enforcement efforts and noting that the FTC has the “biggest hammer” here).
174. *See, e.g.*, Tr. at 127 (Michael McGuffin).
175. *Id.*
176. *See, e.g.*, Tr. at 137-38 (John Cordaro) (expressing support for the workshop and for a cooperative approach to fighting false weight-loss ads); Tr. at 142 (Dr. Harry Greene) (proposing various non-law enforcement options); Tr. at 151 (David Seckman) (expressing support for FTC’s proposal to offer guidance on false claims).
177. *See* Tr. at 123-26, 143, 150-51.
178. *Id.*
179. Tr. at 123-24 (Lisa Myers).
180. *Id.* at 123.
181. *Id.* at 124.
182. *Id.*
183. Tr. at 150 (David Seckman).
184. *Id.*
185. *Id.* at 151. NNFA also supplements self-regulation with consumer education. The association has a “What You Should Know About . . .” series of consumer education pamphlets that are distributed in retail health food stores. *See id.* at 150-51; NNFA Comment (cited in note 156) at 2.
186. Tr. at 143 (John Cordaro).
187. Tr. at 124-25 (Lisa Myers).
188. *Id.* at 125.
189. *Id.* at 125-26. In particular, ERA’s representative described a case in which about two-and-a-half to three years passed between the time ERA began preparing a complaint to NAD and the time a final consent decree was signed. Part of the delay occurred because NAD did not look at the show while it was under active investigation by a district attorney’s office. *Id.*

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190. *Id.* at 126.
191. *See* Tr. at 143-44 (John Cordaro).
192. *See id.*
193. *Id.* at 144.
194. *See* Tr. at 127-33, 137, 143-48.
195. *See* Tr. at 127-33 (Michael McGuffin).
196. *Id.* at 128-29. AHPA’s representative explained that the organization’s draft guidelines are based loosely on the *Voluntary Guidelines for Providers of Weight Loss Products or Services* published in 1999 by the Partnership for Healthy Weight Management. AHPA felt that the Partnership’s guidelines are inapposite to its members because they are directed toward weight-loss clinics and programs, and products sold in conjunction with these clinics and programs, rather than stand-alone dietary supplements. *Id.* at 128.
197. *Id.* at 129-32. Other recommendations in the guidelines may be to instruct users to follow the label and not take more than the recommended dose, and to avoid the use of absolute safety claims (“100 percent safe”) and the statement “FDA approved.” *Id.* at 131-32.
198. *See* Tr. at 137 (John Cordaro) (complimenting AHPA on the advance work done in developing guidelines that could be useful throughout the dietary supplement industry); NNFA Comment (cited in note 156) at 2 (stating that NNFA supports the development of guidelines to assist the industry in lawfully selling products); ERA Comment I (cited in note 169) at 7 (noting that ERA would be happy to discuss the possibility of creating guidelines specific to weight-loss advertising with the FTC staff).
199. *See* Tr. at 143-47 (John Cordaro). CRN and the Office of Dietary Supplements at the National Institutes of Health convened a group of scientists and representatives from interested organizations to assess whether children under the age of 18 should be using sports supplement products. The group prepared guidelines that divided products into red, yellow, and green light categories, and CRN members agreed not to market red or yellow light products to anyone under 18. Green light products are normal nutritional products that are acceptable for any age. *See id.*
200. *Id.* at 149-50.
201. Tr. at 167-68 (Michael McGuffin).
202. *Id.* at 133-34.
203. Tr. at 151 (David Seckman).
204. Tr. at 136 (Lisa Myers); *see also* ERA Comment I (cited in note 169) at 3-4.
205. Tr. at 136 (Lisa Myers).
206. *See id.* at 134-36; *see also* ERA Comment I (cited in note 169) at 4; ERA Comment II (cited in note 18) at 5.
207. Tr. at 135 (Lisa Myers).
208. *Id.* at 136. ERA’s panelist said the science panel’s votes were clear, but she felt there was ambiguity concerning some of the topics discussed. She said ERA did not oppose “the

principles,” but wants to see advertising claims continue to be evaluated in the context in which they are made. *See id.* at 134.

209. Tr. at 139 (Dr. Harry Greene).

210. *Id.*

211. *See* NNFA Comment (cited in note 156) at 2.

212. *Id.*

213. *See* Tr. at 152-70. The National Advertising Division of the Council of Better Business Bureaus was created in 1971 as the advertising industry’s self-regulatory forum. *Id.* at 115, 119. More than 3,800 advertising cases have been resolved successfully through this system. *See* <http://www.nadreview.org/MemberShip.asp?SessionID=83641>.

214. *See* Tr. at 152-56 (Andrea Levine).

215. *Id.* at 152-53.

216. *Id.* at 153-54.

217. *Id.* at 154.

218. *Id.*

219. Tr. at 151 (David Seckman).

220. Tr. at 118-19 (John Cordaro).

221. Tr. at 159 (Andrea Levine).

222. *Id.*

223. *See* Tr. at 160-61 (Lewis Shender).

224. *See* Tr. at 161-62 (Brad Bearnson).

225. *Id.* The panelist referred to these entities as “pop-up” companies. *Id.* at 161.

226. *See id.*

227. *See id.* ICON also recognized that these companies pose enforcement challenges for the FTC. *See id.* at 171.

228. *See* Tr. at 162 (Andrea Levine).

229. *See id.*

230. Tr. at 160-61 (Lewis Shender).

231. *See* discussion at Section II.B.2; Tr. at 125-26.

232. *See* Tr. at 164-65. The Children’s Advertising Review Unit (“CARU”), founded in 1974, is a specialized unit within NAD focused exclusively on children’s advertising. CARU evaluates child-directed advertising and promotional material in all media and works to correct problematic ads. *See* <http://www.caru.org/about/index.asp>.

233. *See* Tr. at 165 (Andrea Levine).

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234. *See* Tr. at 166-70 (David Seckman, Michael McGuffin, John Cordaro).
235. *See id.* CRN said despite the funding challenges, it believes tougher self-regulation is coming and industry leaders who want to be responsible and gain a competitive advantage over egregious players will invest in a system that provides some return on their dollar. *See* Tr. at 169 (John Cordaro).
236. Bob Belive, “Public Comment on Deceptive Weight Loss Advertising Workshop,” Jan. 16, 2003.
237. Kathy J. Kater, LICSW, Public Comment, Oct. 11, 2002 at 4.
238. *See* Tr. at 132 (Michael McGuffin).
239. *Id.*
240. Tr. at 137-38 (John Cordaro).
241. *See id.* at 170.
242. Tr. at 158-59 (Andrea Levine).
243. *See* Partnership website at <http://www.consumer.gov/weightloss/index.htm>.
244. Tr. at 139-41(Dr. Harry Greene). The Partnership for Healthy Weight Management published “Voluntary Guidelines for Providers of Weight Loss Products or Services” in February 1999, which are available at <http://www.ftc.gov/bcp/online/pubs/buspubs/wgtguide.pdf>.
245. *Id.* at 142.
246. *Id.* The International Food Information Council is an educational organization supported by the food industry and involved in food and health issues worldwide. *Id.*
247. *See* Tr. at 171 (John Cordaro). ERA also supported the idea of the FTC, industry, and media partnering in education, both for businesses and consumers. *See* Tr. at 173 (Lisa Myers); ERA Comment II (cited in note 18) at 13.
248. The panelists were John Kimball of the Newspaper Association of America (“NAA”); Ellen Levine, the Editor-in-Chief of *Good Housekeeping Magazine*; Don McLemore, Vice President of Standards at *New Hope Natural Media* Publications; Dean Wil Norton of the University of Nebraska-Lincoln’s Journalism School; Joseph Ostrow of the Cable Advertising Bureau (“CAB”); Michael Pashby of the Magazine Publishers of America (“MPA”); Professor Herbert Rotfeld of Auburn University; and Professor Frederick Schauer of Harvard Law School and the Kennedy School of Government. *See* Appendix A for biographical sketches of the panelists.
249. *See* Section II.B.1.
250. The cable, newspaper, and magazine industries, through their respective trade groups, CAB, NAA, and MPA, are the only media groups that have participated publicly in the discussion. Because public data on the topic are scarce, the staff primarily has relied on information supplied by these three media trade groups to discern how the media currently clear advertisements.
251. Studies conducted in the early nineties found no discernible pattern in how different media outlets review ads. *See* Herbert J. Rotfeld, *Power and Limitations of Media Clearance Practices and Advertising Self-Regulation*, 11 J. Pub. Pol’y & Marketing 87 (1992); Herbert J. Rotfeld *et al.*, *Radio Station Standards for Acceptable Advertising*, 24 J. Bus. Research 361 (1992); Herbert J.

Rotfeld and Patrick R. Parsons, *Self Regulation and Magazine Advertising*, 18 J. of Advertising 33 (1989). This research, however, did not cover the cable industry, which was a fledgling industry 10 years ago. Tr. at 210 (Joseph Ostrow).

252. See Tr. at 192-93 (Ellen Levine); see also Joint MPA/NAA Comment (cited in note 24) at 2-3.
253. See Tr. at 183 (Prof. Herbert Rotfeld); see also Tr. at 185 (John Kimball); Tr. at 188 (Joseph Ostrow).
254. See Tr. at 185 (John Kimball).
255. See, e.g., Tr. at 185 (John Kimball); Tr. at 189 (Michael Pashby).
256. The Cable Advertising Bureau (“CAB”) represents more than 60 cable networks and cable operators. Together, its members comprise 85% of the cable outlets that broadcast advertising and are responsible for 95% of the cable advertising. See Comments of the National Cable and Telecommunications Association and the Cabletelevision Advertising Bureau (“CAB Comment”), Oct. 29, 2002 at 1. CAB is a subgroup of the National Cable and Telecommunications Association, the principal trade association for the cable television industry. See also Tr. at 177 (Joseph Ostrow).
257. See Tr. at 187 (Joseph Ostrow).
258. See CAB Comment (cited in note 256) at 3-4 (referencing the “Cabletelevision Advertising Bureau Voluntary Guidelines For Commercial Standards and Practices,” which is attached to the comment).
259. See Tr. at 187-88 (Joseph Ostrow). CAB’s representative pointed out that because reputable research companies do not collect data on local cable, it is difficult to obtain solid information on how ad review is handled by cable outlets. *Id.* at 209-10.
260. See Tr. at 188. For example, a religious channel’s standards will most likely differ from those of other cable channels. *Id.*
261. See CAB Comment (cited in note 256) at 2.
262. See *id.*
263. See *id.* CAB’s comment further explained that, despite collecting licensing fees from the cable systems, cable networks rely on ad sales as a principal source of revenue. See *id.* at 3.
264. The Newspaper Association of America (“NAA”) is the trade group for over 2,000 U.S. and Canadian newspapers. See Tr. at 175 (John Kimball); Comments of the Newspaper Association of America (“NAA Comment”), Oct. 29, 2002 at 1. Its membership accounts for nearly 90% of the U.S. daily newspapers. See *id.*
265. Tr. at 187 (John Kimball); see also NAA Comment (cited in note 264) at 3.
266. *Id.* at 186; see also NAA Comment (cited in note 264) at 3.
267. See Tr. at 185 (John Kimball). NAA explained that, with some ads, errors are “obvious,” such as when an ad lists the price of the product with all zeros, and as a result, ad personnel may be prompted to contact the advertiser. See *id.* at 186-87.
268. See Tr. at 185 (John Kimball).

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269. *See id.*
270. *See id.* The NAA representative remarked that “[w]e don’t catch it all, but we try very hard.” *Id.* Another panelist, who has extensively researched clearance standards, commented that he has found newspapers are more likely than other media to reject an ad on the grounds that it is misleading. Tr. 183-84 (Herbert Rotfeld).
271. *See id.* at 187.
272. The Magazine Publishers of America (“MPA”) currently represents 240 U.S. companies that publish over 1,400 magazines. Joint MPA/NAA Comment (cited in note 24) at 1; *see also* Tr. at 178 (Michael Pashby).
273. *See* Tr. at 188 (Michael Pashby).
274. *Id.*
275. *Id.*
276. *Id.* at 188-89.
277. *See id.* at 189.
278. *See* Tr. at 191-93 (Ellen Levine); Tr. at 195-96 (Don McLemore). *Good Housekeeping Magazine* administers a sixteen-point guide that is used to evaluate diet and weight programs and plans in particular. Tr. at 192.
279. *See* Tr. at 191-92 (Ellen Levine).
280. Tr. at 209 (Joseph Ostrow); *see also* Tr. at 202-04, 219 (Michael Pashby); NAA Comment (cited in note 264) at 2; CAB Comment (cited in note 256) at 4; Joint MPA/NAA Comment (cited in note 24) at 2-3.
281. *See* Joint MPA/NAA Comment (cited in note 24) at 2-3.
282. *See* Tr. at 206-07 (Joseph Kimball).
283. *See* Tr. at 203 (Michael Pashby); *see also* Joint MPA/NAA Comment (cited in note 24) at 2; CAB comment (cited in note 256) at 4.
284. *See* Joint MPA/NAA Comment (cited in note 24) at 2. The Good Housekeeping Institute funds *Good Housekeeping Magazine’s* advertising review program. Tr. at 191 (Ellen Levine).
285. *See* CAB Comment (cited in note 256) at 3. The three major broadcast networks require advertisers to supply substantiation in support of each ad claim. This substantiation is reviewed by the networks prior to dissemination of the ad. *See, e.g., Advertising Standards and Guidelines*, ABC, Inc., Department of Broadcast Standards and Practices, March 2001 (Update), available at http://www.espnabcsportscms.com/adsales/stuff/ABC_Advertising_Standards_and_Guidelines.pdf.
286. *See* CAB Comment (cited in note 256) at 3. On average, it costs \$116,000 to purchase a 30-second spot on a major broadcast network, but only \$11,000 on a cable network. *See id.*
287. *See* ERA Comment II (cited in note 18) at 14.
288. *See* Tr. at 209-10 (Joseph Ostrow); *see also* NAA Comment (cited in note 264) at 4.

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289. CAB Comment (cited in note 256) at 2; *see also* Tr. at 210 (Joseph Ostrow). These ad sales account for about 7% of cable systems' total revenues. CAB Comment (cited in note 256) at 2.
290. In total, there are 120 cable networks that carry advertising; of these, approximately 60 are CAB members. CAB Comment (cited in note 256) at 3.
291. *Id.* On the other hand, CAB pointed out in its written comment that the three major broadcast networks, ABC, NBC, and CBS, sell a total of 450,000 units of advertising, which breaks down to approximately 150,000 units per network. *Id.* This is nearly 30% less than the average number of units sold by a cable network company.
292. *See* Tr. at 185-86 (John Kimball). On the other hand, Prof. Herbert Rotfeld, a marketing professor who served on the panel, conducted research that suggested the costs of conducting ad review in the particular category of weight-loss would be minimal because the ads are often "repeat" ads and do not present new claims for review each time. *See* Tr. at 222-23.
293. *See* Tr. at 185-86, 219 (John Kimball); *see also* NAA Comment (cited in note 264) at 4.
294. Tr. at 192 (Ellen Levine).
295. NAA Comment (cited in note 264) at 4.
296. *See* Tr. at 193-94 (Ellen Levine).
297. *Id.*
298. *See* Tr. at 195 (Don McLemore).
299. *Id.*
300. Tr. at 226 (John Kimball); *see also* Joint MPA/NAA Comment (cited in note 24) at 21.
301. *See* Tr. at 230 (Michael Pashby).
302. *See* Tr. at 227 (Ellen Levine).
303. Tr. at 228-29 (Joseph Ostrow).
304. ERA Comment II (cited in note 18) at 13.
305. *See* Tr. at 227 (Ellen Levine).
306. NAA Comment (cited in note 264) at 3.
307. CAB Comment (cited in note 256) at 5.
308. *See* Tr. at 225 (Wil Norton).
309. *See* Tr. at 227 (John Kimball).
310. *See* Tr. at 229 (Joseph Ostrow).
311. *See* Tr. at 219 (John Kimball).
312. *See id.*
313. *See* Joint MPA/NAA Comment (cited in note 24) at 11.
314. *See* ERA Comment I (cited in note 169) at 4-5.

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315. *See* Tr. at 204 (Michael Pashby).
316. *See* Tr. at 218-19 (Michael Pashby); Joint MPA/NAA Comment (cited in note 24) at 11; ERA Comment II (cited in note 18) at 8. In their comments to the FTC, the Magazine Publishers of America, Inc. (“MPA”) and the Newspaper Association of America (“NAA”) expressed concern that publishers who voluntarily use FTC guidance to screen advertisements for weight-loss products will assume a duty that subjects them to increased liability for harm caused to consumers. Joint MPA/NAA Comment (cited in note 24) at 15-19; NAA Comment (cited in note 264) at 5-6. It is unlikely, however, that publishers who screen advertisements will be exposed to increased liability unless they (1) increase the risk of harm to the consumer or (2) cause the consumer to rely on the screening to the consumer’s peril. *See* Restatement (Second) of Torts § 323(a) and (b); 57A Am. Jur. 2d Negligence § 113 (1989). Applying these tests, it is clear that (1) publishers who screen out false weight-loss claims will decrease the risk of harm to consumers and (2) publishers will not cause consumers to rely on their screening process unless publishers make guarantees about their screening process. *See Pittman v. Dow Jones*, 662 F. Supp. 921, 923 (E.D. La. 1987) (Wall Street Journal has no special duty to readers unless it guarantees the soundness of the products that it advertises even though it is held in high esteem); *compare Hanberry v. Hearst Corp.*, 276 Cal. App. 2d 680, 684 (1969) (*Good Housekeeping Magazine* “in effect loaned its reputation to promote and induce [sales]” by publishing advertisements with its Good Housekeeping Consumers’ Guaranty Seal).
317. *See id.*
318. *See* CAB Comment (cited in note 256) at 4; ERA Comment II (cited in note 18) at 8; *see also* Joint MPA/NAA Comment (cited in note 24) at 3, 11.
319. Joint MPA/NAA Comment (cited in note 24) at 3-10.
320. *See* Tr. at 211-216.
321. Although this report concludes that this claim is not scientifically feasible when made in the context of an ad promising substantial weight loss, it has not been included in the guidance because it does not appear to be widespread.
322. The claim that “consumers who use the advertised product can lose weight only from those parts of the body where they wish to lose weight” is not included. *See id.*
323. As noted in this report, covered products include only nonprescription drugs, dietary supplements, creams, wraps, devices, patches, and similar products. Of course, claims for other weight-loss products or services, as well as other claims for the covered products, may also be false or misleading.
324. *See* Tr. at 210.
325. *See* Tr. at 194 (Ellen Levine); Tr. at 195 (Don McLemore).
326. The dissemination of such claims is subject to the constraints of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52 (a), (b) (2003). Section 5(a) of the FTC Act authorizes the Commission to prohibit “unfair or deceptive acts or practices in or affecting commerce.” 15 U.S.C. § 45(a). Further, under Section 12(a) of the FTC Act, it is “unlawful for any person, partnership, or corporation to disseminate, or cause to be disseminated, any false advertisement... for the purpose of inducing, or which is likely to induce... the purchase of food, drugs, devices, services, or cosmetics.” 15 U.S.C. § 52(a). And finally, Section 12(b) provides

that “the dissemination or the causing to be disseminated of any false advertisement” proscribed by Section 12(a) is a violation of Section 5 of the FTC Act. 15 U.S.C. § 52(b).

327. *See* Tr. at 189 (Michael Pashby); *see also* Joint MPA/NAA Comment (cited in note 24) at 7. According to MPA and NAA, “an ‘on their face’ standard may also work when it comes to proffered advertisements that ‘clearly’ propose illegal activity” because “a person reviewing [the ad] can determine whether to reject it simply by looking at it and noticing whether it addresses a certain topic.” *See id.* The goal of the guidance piece is to facilitate a similar process for certain types of weight-loss ads.
328. *See* Tr. at 218-19 (Michael Pashby); *see also* Joint MPA/NAA Comment (cited in note 24) at 5-6; ERA Comment II (cited in note 18) at 4-6.
329. *See, e.g., FTC v. No. 9068-8425 Quebec, Inc. d/b/a Bio Lab*, No. 1:02:CV-1128 (N.D.N.Y. July 28, 2003) (stipulated final judgment). Of course, in any enforcement action, the Commission retains the burden of proving that the claims are false, deceptive, or unsubstantiated.

Appendix A: Biographical Sketches of Panelists

Science Panel

Anthony L. Almada, B.Sc., M.Sc.

Mr. Almada is President, founder, and Chief Scientific Officer of IMAGINutrition, Inc., an innovation and science marketing think tank focusing on nutritional technologies, IP clinical research validation, and science-driven media campaigns. IMAGINutrition is currently engaged in multiple clinical studies in various universities around the world. It is also prosecuting several patents and functioning as a technology transfer entity for process, composition and utility patents in the human and animal dietary supplement, cosmeceutical and functional beverage and food sectors. Mr. Almada has worked in the dietary supplement industry since 1975. In 1992 he co-founded Experimental and Applied Sciences (EAS), now the largest sports nutrition company on a global scale. During his tenure as Chief Scientific Officer and President, he developed a university research program that completed over 15 clinical studies in the first three years of the company's history and yielded two issued patents. After selling EAS, he co-founded a medical food company that developed a clinically-validated product to prevent HIV wasting. A nutritional and exercise biochemist, Mr. Almada has collaborated on over 50 university clinical trials, ranging from AIDS/HIV wasting to weight loss and gain. He earned his undergraduate degree in physiology and nutritional biochemistry at the University of California, Irvine and California State University, Long Beach, and his graduate degree at the University of California, Berkeley, exploring the impact of exercise on tissue antioxidant status and kinetics, including vitamins C and E, coenzyme Q, and glutathione.

George Blackburn, M.D., Ph.D.

Dr. Blackburn is Associate Director of the Division of Nutrition, Associate Professor of Surgery and Nutrition, and the first incumbent of the S. Daniel Abraham Chair in Nutrition Medicine at Harvard Medical School. Dr. Blackburn is also Director of the Center for the Study of Nutrition Medicine and Chief of the Nutritional/Metabolism Laboratory, affiliated with the Beth Israel Deaconess Medical Center in Boston. His laboratory investigates complex issues dealing with nutrition and health, and he has published widely on various aspects of nutrition, medicine, and metabolism with over 400 publications to date. Dr. Blackburn is a Past President of the North American Association for the Study of Obesity, the American Board of Nutrition, and the American Society for Clinical Nutrition. He serves on the Board of Advisors for the American Society of Parenteral and Enteral Nutrition and on the Scientific Advisory Committee of the C. Everett Koop Foundation Shape Up America Campaign. He is a member of the board of the American Obesity Association and was Chairman of the Massachusetts Medical Society Committee on Nutrition from 1992-1999. Dr. Blackburn is a principal or co-principal investigator on several NIH grants, including the Look AHEAD study, and is Associate Director of the NIH Boston Obesity Nutrition Research Center. Dr. Blackburn received his medical degree from the University of Kansas and completed his internship and residency at Boston City Hospital, Harvard Medical School. He earned his doctorate in nutritional biochemistry from the Massachusetts Institute of Technology.

Denise Bruner, M.D.

Dr. Bruner is Chairman of the Board of the American Society of Bariatric Physicians (ASBP). She also serves as Co-Chair of the ASBP's Strategic Planning Committee, and previously served as the organization's President. Dr. Bruner has testified on behalf of the ASBP before Congress, the Virginia Board of Medicine, and the National Institutes of Health's National Task Force on Prevention

and Treatment of Obesity. She has also appeared as a representative of ASBP, and to discuss various bariatric topics, on several television programs, including NBC's Today Show, Fox Morning News, the Montel Williams Show and the Maury Povich Show. Dr. Bruner has a private practice in Arlington, Virginia, where she specializes in bariatric medicine and family practice. She is also on active staff at Arlington Hospital. Dr. Bruner is certified by the American Board of Bariatric Medicine, and serves on the Advisory Council of the American Obesity Association. She has been quoted in numerous publications including the *Washington Post*, *New York Times*, *Wall Street Journal*, *Washington Times*, *Shape*, *Good Housekeeping*, *Self*, *People*, and *Prevention*. Dr. Bruner is a graduate of the George Washington University and Howard University College of Medicine.

Harry Greene, M.D.

Dr. Greene is Medical Director and Vice President for Research and Medical Education for Slim Fast Foods Company. He is responsible for new research programs and the education of physicians on the use of Slim Fast products. Personnel under his guidance coordinate and integrate a five-million-dollar-a-year program in obesity research and medical marketing. Prior to joining Slim Fast, he served as Senior Director of Medical Affairs for Bristol-Myers Squibb Mead Johnson Nutritional Group, Director of the Clinical Nutrition Research Unit at Vanderbilt University Medical Center, and Chief of Pediatric Gastroenterology and Nutrition and Professor of Pediatrics and Biochemistry at Vanderbilt. An internationally recognized nutrition research specialist and pediatric gastroenterologist, Dr. Greene has served as President of the North American Society of Pediatric Gastroenterology/Nutrition and President of the American Society for Clinical Nutrition. He has published over 200 articles in peer-reviewed medical journals on such topics as gastrointestinal adaptation during health and disease, pathophysiology and treatment of type I glycogen storage disease, vitamins in health and disease, and lipids. Dr. Greene also participates on behalf of Slim Fast in the Partnership for Healthy Weight Management. Dr. Greene earned his bachelor's degree from Baylor University and his medical degree from Emory University School of Medicine.

Steven Heymsfield, M.D.

Dr. Heymsfield is Deputy Director of the Obesity Research Center and Director of the Human Body Composition Laboratory and Weight Control Unit at St. Luke's-Roosevelt Hospital Center in New York. He is also a Professor of Medicine at Columbia University College of Physicians and Surgeons and a Visiting Scientist at Rockefeller University and the Brookhaven National Laboratory. Dr. Heymsfield has published more than 200 articles covering topics such as obesity, anorexia nervosa, bulimia nervosa, malnutrition, pregnancy, body composition, and caloric expenditure. Dr. Heymsfield has helped to design and build two whole-body human calorimeters, including a direct gradient-layer system and a ventilated chamber indirect calorimeter. He also pioneered new methods of assessing human body composition such as computed tomography, magnetic resonance imaging, multicompartiment methods and bioimpedance analysis. His recent research includes energy metabolism, obesity, body composition, and effectiveness/safety of weight loss treatments. Dr. Heymsfield is President of the American Society of Clinical Nutrition and was formerly President of the American Society of Parenteral and Enteral Nutrition. He is an Honorary Member of the American Dietetic Association, the Chilean Clinical Nutrition Association, the Latin American and Argentine Medical Association, and the New York Dietetic Association. Dr. Heymsfield received his bachelor's degree from Hunter College and his degree in medicine from Mount Sinai School of Medicine in New York.

Van Hubbard, M.D., Ph.D.

Dr. Hubbard is Director of the Division of Nutrition Research Coordination and Chief of the Nutritional Sciences Branch of the Division of Digestive Diseases and Nutrition, National Institute of

Diabetes and Digestive and Kidney Diseases, at the National Institutes of Health (NIH). Within the Division of Digestive Diseases and Nutrition, he is the Director of the Clinical Nutrition Research Units and Obesity/Nutrition Research Centers Programs, and is responsible for development of research initiatives and management of research programs related to the nutritional sciences and obesity. His major research interests are clinical nutrition, obesity, cystic fibrosis, essential fatty acid metabolism, and nutritional modulation of disease risk. Dr. Hubbard is the current Chair of the NIH Nutrition Coordinating Committee and is the Department of Health and Human Services liaison for the Interagency Committee on Human Nutrition Research. Dr. Hubbard serves as the NIH representative on numerous committees, serves on various Healthy People 2010 work groups, and is co-lead for the Nutrition and Overweight Focus Area and the development of the Surgeon General's Initiative to address overweight and obesity. He previously served as a Professor of Pediatrics at the Uniformed Services University of the Health Sciences and a member of the Board of Directors of the American Board of Nutrition. Dr. Hubbard received his Ph.D. in biochemistry and his M.D. from the Medical College of Virginia, Virginia Commonwealth University.

Judith S. Stern, S.M., Sc.D.

Dr. Stern is a Professor in the Departments of Nutrition and Internal Medicine, Division of Clinical Nutrition and Metabolism, at the University of California, Davis. She is also the Director of the Food Intake Laboratory Group at UC-Davis. An expert on diet and nutrition, Dr. Stern has published extensively on nutrition, the effect of exercise on appetite and metabolism, and obesity. She is currently studying the effects of obesity on lipids and renal disease and the effects of a non-diet approach to health in obese women. She is Program Co-Director of a nutrition training grant and Co-Director of a Clinical Nutrition Unit Core Laboratory funded by the National Institutes of Health. Dr. Stern has published over 200 research papers in professional journals and over 150 articles in popular magazines such as *Redbook* and is an Editorial Advisor to *Prevention* Magazine. Dr. Stern is a member of numerous professional organizations, including the American Society for Clinical Nutrition, where she was President from April 1996 to April 1997, and the North American Association for the Study of Obesity, where she was President from September 1992 to October 1993. She is co-founder and Vice President of The American Obesity Association, a lay advocacy organization dedicated to advancing understanding of the disease of obesity. Dr. Stern received her bachelor degree in Foods and Nutrition from Cornell University and her master of science and doctor of science degrees in nutrition from the Harvard University School of Public Health in Boston.

Lawrence Stifler, Ph.D.

Dr. Stifler is President of Health Management Resources (HMR), the leading provider of weight treatment programs and training to the medical community. Used by several hundred hospitals, HMOs, group medical practices and research centers, HMR provides to these programs ongoing operational and program support, nutritional products, staff training, and research. Dr. Stifler, who is a behavioral psychologist with more than 35 years experience researching and developing programs in behavioral medicine with a specialization in weight management and lifestyle-related health issues, helped design HMR's medically and non-medically supervised weight and health management programs. Dr. Stifler has also lectured extensively on such topics as weight management, exercise, preventive health, nutrition, cardiac rehabilitation, smoking cessation, and psychopharmacology. He has published research, written numerous training manuals and materials, and presented at many professional conferences including the International Congress on Obesity, North American Association for the Study of Obesity, Harvard Medical School's Obesity Conference, the National Conference on Hypertension, the American College of Nutrition, the Society for Behavioral Medicine, the American Dietetic Association, and the American Psychological Association. Dr. Stifler has had numerous faculty and teaching

appointments at Boston University, Harvard University, and Northeastern University, and has been quoted extensively by print, radio, and television, including numerous appearances on Good Morning America. Dr. Stifler is an avid exerciser who has won many age class road races, and recently, at age sixty, completed his tenth marathon.

Thomas Wadden, Ph.D.

Dr. Wadden is Director of the Weight and Eating Disorders Program and a Professor of Psychology at the University of Pennsylvania School of Medicine. Dr. Wadden's principal research is on the treatment of obesity by methods that have included behavior modification, very-low-calorie diets, exercise, and medication. He has also investigated the psychological effects of obesity and weight loss. He has published over 180 scientific papers and co-edited three books, the most recent of which is *Handbook of Obesity Treatment* (with Dr. Albert Stunkard). His research is supported by grants from the National Institutes of Health, as well as from industry. Dr. Wadden serves on the National Task Force on the Prevention and Treatment of Obesity and on the editorial boards of *International Journal of Eating Disorders*, *Journal of Consulting and Clinical Psychology*, and *Obesity Research*. He also serves as Chair of the Lifestyle Intervention Subcommittee for the Look AHEAD study, a 12-year, NIH-supported study investigating the health consequences of intentional weight loss in obese individuals with type 2 diabetes. Dr. Wadden received his A.B. from Brown University and his doctorate in clinical psychology from the University of North Carolina at Chapel Hill.

Susan Yanovski, M.D.

Dr. Yanovski is Director of the Obesity and Eating Disorders Program at the National Institutes of Health. She is also Executive Director of the National Task Force on Prevention and Treatment of Obesity in the Division of Digestive Diseases and Nutrition at NIH's National Institute of Diabetes and Digestive and Kidney Diseases. Prior to joining NIH, Dr. Yanovski worked as an urgent care physician, a physician at Comprehensive Weight Control in Rockville, Maryland, and a research associate at the National Institute of Mental Health. Dr. Yanovski is certified by the American Board of Nutrition and is a fellow of the North American Association for the Study of Obesity. She serves on several committees and working groups, including the Department of Health and Human Services Girls and Obesity Steering Committee, the NIH Nutrition Coordinating Committee, and the Weight-Control Information Network Executive Committee. Dr. Yanovski received her medical degree from the University of Pennsylvania and her bachelor's degree in social work from Widener University.

Industry Panel

Brad Bearnson, Esq.

Mr. Bearnson has been General Counsel of ICON Health & Fitness, Inc., the world's largest manufacturer of home fitness and exercise equipment, since 1995. In this capacity, he is involved on a daily basis with product liability and safety issues. Mr. Bearnson also co-founded Bearnson & Peck, L.C., in 1999, and served as a Member of the Legislative Affairs Committee of the Utah State Bar from 1997 to 2000. He began practicing law in Logan, Utah, with the law firm of Olson & Hoggan, P.C., and served as Managing Attorney for several years. Mr. Bearnson obtained his Bachelor of Science degree from Utah State University and his law degree from the University of Utah. He obtained his Certified Public Accountant certificate in 1981 and was admitted to the Utah State Bar in 1982. He has also been admitted to practice in various courts across the nation.

John Cordaro

At the time of the workshop, Mr. Cordaro was President and Chief Executive Officer of the Council for Responsible Nutrition (CRN), an association of the dietary supplement industry. Heading the organization since 1982, Mr. Cordaro provided the leadership for CRN to become a full-service trade association recognized as a leading association in the dietary supplement industry. He served as a spokesperson for the multi-billion dollar industry through frequent print and electronic media responses as well as various public and private forums. Mr. Cordaro has more than 35 years experience in domestic and international food, nutrition, and agricultural activities, including senior positions with the Food Safety Council, Inc., the U. S. Congress Office of Technology Assessment, and the U.S. Department of State Agency for International Development. His numerous publications appear in popular magazines and in specialized and technical journals. Mr. Cordaro graduated from Loyola University of the South with a B.S. in government, economics, and philosophy. He later attended the Georgetown University Graduate School of Foreign Service and received his advanced degree in agricultural economics with a special emphasis on nutrition policy planning from Cornell University.

Harry Greene, M.D.

Dr. Greene is Medical Director and Vice President for Research and Medical Education for Slim Fast Foods Company. He is responsible for new research programs and the education of physicians on the use of Slim Fast products. Personnel under his guidance coordinate and integrate a five-million-dollar-a-year program in obesity research and medical marketing. Prior to joining Slim Fast, he served as Senior Director of Medical Affairs for Bristol-Myers Squibb Mead Johnson Nutritional Group, Director of the Clinical Nutrition Research Unit at Vanderbilt University Medical Center, and Chief of Pediatric Gastroenterology and Nutrition and Professor of Pediatrics and Biochemistry at Vanderbilt. An internationally recognized nutrition research specialist and pediatric gastroenterologist, Dr. Greene has served as President of the North American Society of Pediatric Gastroenterology/Nutrition and President of the American Society for Clinical Nutrition. He has published over 200 articles in peer-reviewed medical journals on such topics as gastrointestinal adaptation during health and disease, pathophysiology and treatment of type I glycogen storage disease, vitamins in health and disease, and lipids. Dr. Greene also participates on behalf of Slim Fast in the Partnership for Healthy Weight Management. Dr. Greene earned his bachelor's degree from Baylor University and his medical degree from Emory University School of Medicine.

Andrea Levine, Esq.

Ms. Levine is Director of the National Advertising Division (NAD) of the Council of Better Business Bureaus, the advertising industry's forum for voluntary self-regulation of national advertising. Over the course of her legal career, Ms. Levine has handled a wide range of advertising challenges, including drafting a comprehensive blueprint for truthful and accurate airline advertising, formulating advertising guidelines for car rentals at the request of the industry, analyzing and evaluating environmental marketing claims, and handling product safety issues particularly as they pertain to toys and other products intended for use by children. During the ten years that she served as an Assistant Attorney General for the State of New York, Ms. Levine worked closely with the FTC, state attorneys general nationwide, FDA, EPA, and CPSC. Before joining NAD, Ms. Levine was special counsel to the Ryan Community Health Network, a non-profit managed care company. She received her B.A. from New York University and her J.D. from Brooklyn Law School.

Michael McGuffin

Mr. McGuffin is President of the American Herbal Products Association (AHPA), the primary U.S. trade group for herbal products manufacturers. He also serves as Treasurer and a member of the Board of Trustees for the non-profit American Herbal Pharmacopoeia, and is Chair of the Industry Committee of the Plant Conservation Alliance/Medicinal Plant Working Group. He is a board member of United Plant Savers, and of the Dietary Supplement Education Alliance, a non-profit industry-funded educational resource committed to providing accurate information about supplements to consumers. Mr. McGuffin has been active in the herbal industry since 1975, having owned both retail and manufacturing businesses in the field. He is the Managing Editor of AHPA's Botanical Safety Handbook (1997) and Herbs of Commerce, 2nd edition (2000). He has represented the herbal industry at state and federal hearings on herbal regulatory issues and as a member of the FDA's Food Advisory Committee Working Group on Good Manufacturing Practices for Dietary Supplements. Mr. McGuffin has been quoted in a variety of news publications such as the *New York Times*, *Washington Post*, *U.S. News & World Report*, and *Newsweek*, and has made appearances on ABC's Nightline, National Public Radio, and ABC Radio.

Elissa Matulis Myers

At the time of the workshop, Ms. Myers was President and CEO of the Electronic Retailing Association (ERA), a trade association representing the \$125 billion electronic retailing industry. Founded in 1990, the ERA is comprised of more than 450 member companies and subsidiaries worldwide that use the power of electronic retailing to sell direct to consumers via television, radio, Internet, and wireless media. During Ms. Myers' tenure, the organization changed its name from the National Infomercial Marketing Association to the Electronic Retailing Association, published the first comprehensive industry guidelines for online marketing, created inter-industry guidelines for Advance Consent Marketing and Telemarketing, and established strong participation in government forums. Ms. Myers also founded ERA Europe, the France-based ERA operation dedicated to helping promote electronic retailing across Europe. Her professional experience includes 25 years of strategic management of associations. She previously served as head of the publishing division at the American Society of Association Executives and developed the ASAE member database, customer service center, the International Section, the Ethics Committee, and group insurance programs. Ms. Myers is a member of the Committee of 100 for the U.S. Chamber of Commerce, the Industry Functional Advisory Committee for the U.S. Department of Commerce, the Board of Directors of the Greater Washington Society of Association Executives and the National Board of Regents of the Institutes for Organization Management.

David Seckman

Mr. Seckman is Executive Director and CEO of the National Nutritional Foods Association (NNFA), the nation's oldest and largest natural products trade organization. Based in California, NNFA represents more than 4,000 manufacturers, distributors, and retailers of natural products including dietary supplements, organic foods, and health and beauty aids. Since joining the organization in May 2000, Mr. Seckman has represented the industry in testimony before Congress about the benefits of healthy lifestyle and food choices, advanced the association's leadership role as a standard setter, and participated in a coalition to educate consumers about the safe and effective use of dietary supplements. He was integral in the formation of the NNFA-China, and spearheaded the revitalization of NNFA's political action committee, expanding the association's advocacy efforts. Mr. Seckman previously served as Vice President for Regulatory Affairs and interim CEO for the American Health Care Association. He holds a master's degree in health care administration from the University of Illinois and a bachelor's degree in political science from George Washington University.

Lewis Shender, Esq.

Mr. Shender joined Jenny Craig, Inc. in June 2002 as Vice President, General Counsel, and Corporate Secretary. He is responsible for providing legal support to all functional areas within the company as well as to the Board of Directors. Mr. Shender joined Jenny Craig after serving as Vice President for Law and Acting General Counsel of Focal Communications Corporation, a national telecommunications provider, and as Vice President and General Counsel of MVE Holdings, Inc., an international manufacturer of liquid gas containment and application systems. Prior to that, Mr. Shender was with the law firm of Dorsey & Whitney, focusing on corporate transactions and venture capital investments. Mr. Shender is a magna cum laude graduate of Duke University and received his law degree from New York University School of Law.

Media Panel

John Kimball

Mr. Kimball is Senior Vice President and Chief Marketing Officer at the Newspaper Association of America (NAA). He is responsible for the NAA's marketing initiatives to increase revenue, grow circulation and readership, and to promote and improve work processes for the \$59 billion newspaper industry. Prior to his post at the NAA, Mr. Kimball served as Senior Vice President of Sales for Macromedia, Inc. where he integrated the sales and marketing strategies for the company's twenty print properties. Mr. Kimball is on the Board of Directors of the Joint Nation Retail Federation/Retail Advertising Marketing Association and has served on the Boards of the Better Business Bureau in Detroit, Denver, and Northern New Jersey. Mr. Kimball, who is a decorated Vietnam Veteran, received a B.A. in advertising from Michigan State University and a graduate degree from the Harvard Business School Executive Management Program.

Ellen Levine

Ms. Levine is Editor-in-Chief of *Good Housekeeping*, the flagship women's publication of Hearst Magazines. She is the first woman to serve in this position since the magazine's inception in 1885. Prior to joining *Good Housekeeping*, Ms. Levine was Editor-in-Chief at two other major women's magazines: *Redbook* and *Women's Day*, and was a Senior Editor at *Cosmopolitan*. Ms. Levine frequently appears on national talk shows and news programs, and has authored numerous books and articles. She served two terms as President of the American Society of Magazine Editors from 1994 to 1996. Throughout her publishing career, Ms. Levine has received many honors, including the Matrix Award for exceptional achievement in the communications industry. Also, in recognition of her work on the U.S. Attorney General's Commission on Pornography, the American Society of Journalists and Authors awarded Ms. Levine for her courage in the Pursuit of Truth. Ms. Levine similarly was honored by the Atlantic Coast Independent Distributors, Inc. for her distinguished service defending the First Amendment and the U.S. Constitution. Ms. Levine is a graduate of Wellesley College.

Don McLemore

Mr. McLemore is Vice President of Standards at New Hope Natural Media, a leading media and trade show company in the natural products industry. In 1998 Mr. McLemore established an in-house Standards Program for the company's Trade Show and Conference Division and in 1999 extended the program to include its Publishing and New Media Division. The Standards Program is designed to support industry self-regulation. Prior to joining New Hope Natural Media, Mr. McLemore was on the staff of the Herb Research Foundation. His extensive clinical experience includes being the Direc-

tor of a Neuro-Vestibular diagnostics center. Mr. McLemore received an M.A. in Audiology from the University of Tulsa.

Dean Wilbert Norton

Dean Norton is Dean of the University of Nebraska's Lincoln College of Journalism and Mass Communications. Dean Norton has served in this post since 1990. He also is a partner-owner of the South Reporter, Inc., a company that publishes two newspapers and a total market publication. He is a trustee of the Freedom Forum and is Vice President of the Accrediting Council on Education in Journalism and Mass Communications. He is a past President of the Association for Education in Journalism and the Association of Schools of Journalism and Mass Communications. Dean Norton's prior experience includes serving as the publisher of the *Daily Iowan*, and the managing editor of Christian Life Publications, Inc. He also was on the staff of the *Chicago Tribune* and was sports editor of the Wheaton, Illinois, *Daily Journal*. Dean Norton has authored numerous journal and magazine articles, has ghost-written three books, and has directed funded research for a dozen newspapers. Dean Norton received his B.A. in history with honors from Wheaton College and his Ph.D. in Mass Communications from the University of Iowa. He also earned an M.A. in mass communications from Indiana University.

Joseph Ostrow

Mr. Ostrow is President and CEO of the Cabletelevision Advertising Bureau (CAB), the national trade association of the cable television industry. The CAB is devoted to the marketing and advertising activities of the cable industry, representing system operators that serve 85% of the nation's cable subscribers. Mr. Ostrow's key responsibilities at the CAB involve developing initiatives to increase advertising revenue for the industry. Prior to joining CAB, Mr. Ostrow served as Executive Vice President, Worldwide Media Director at Foote, Cone & Belding Communications, Inc. where he was responsible for FCB's worldwide media operations. Mr. Ostrow began his career at Young & Rubicam, where he rose to the position of executive vice president, Director of Communication Services. A current Member of the Board of the Advertising Council, Mr. Ostrow is a well-known speaker and writer on issues that affect the advertising community. He previously has served as President of Media Directors Council and the Advertising Information Services and Vice Chairman of the American Association of Advertising Agencies' Media Policy Committee. Mr. Ostrow attended Cornell University and New York University.

Michael Pashby

Mr. Pashby is Executive Vice President and General Manager for the Magazine Publishers of America (MPA). At MPA, among his other responsibilities, Mr. Pashby oversees the Consumer Marketing Department and works on supporting and promoting the magazine industry to its key constituencies. In the past he has coordinated the magazine industry's position on sweepstakes promotions, and has developed "Best Practice" guidelines for the industry in the telemarketing area. Prior to joining MPA, Mr. Pashby was President and Publisher of *Art and Antiques Magazine* and served as Vice President of Circulation and New Product Development for Gruner+Jahr U.S.A. At Gruner+Jahr he was responsible for the circulation of *Parents*, *Young Miss*, and *Expecting*. Mr. Pashby earned his B.A. from Warwick University, England.

Professor Herbert Rotfeld

Prof. Rotfeld is a Professor of Marketing at Auburn University and author of the book *Adventures in Misplaced Marketing*. A respected scholar of advertising regulation and self-regulation, Professor Rotfeld is the editor of the *Journal of Consumer Affairs* and serves on the editorial boards of several

other research journals. Professor Rotfeld is the recipient of the American Academy of Advertising's Outstanding Contribution to Research Award in 2000, and was a columnist in *Marketing News* magazine and a contributing section editor for the *Journal of Consumer Marketing*. Professor Rotfeld received his B.A. and Ph.D. in Communications from the University of Illinois at Urbana-Champaign.

Professor Frederick Schauer

Prof. Schauer is the Frank Stanton Professor of the First Amendment at the John F. Kennedy School of Government of Harvard University. Professor Schauer is a widely recognized scholar on the First Amendment and his work has been the subject of numerous academic commentaries. He is the author of more than 125 articles on constitutional law and has written several books on the topic, including the *Law of Obscenity*, *Free Speech: A Philosophical Enquiry*, and *Playing By the Rules: A Philosophical Examination of Rule-Based Decision Making in Law and in Life*. Professor Schauer is the former chair of the Association of American Law Schools Section on Constitutional Law and is a Fellow of the American Academy of Arts and Sciences, as well as the Radcliffe Institute of Advanced Study. He is co-founder and co-editor of the journal *Legal Theory*. In addition to appearing before many congressional committees on the First Amendment and freedom of speech, Professor Schauer has taught and advised countries worldwide on various issues concerning legal and constitutional development. Professor Schauer is a graduate of Dartmouth College, the Amos Tuck School of Business Administration at Dartmouth, and the Harvard Law School.



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