

WRITTEN Testimony
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on behalf of the
Council for Responsible Nutrition (CRN)

“Protecting Consumers from False and Deceptive Advertising of Weight-Loss Products”

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Good morning. My name is Steve Mister, and I am the President & CEO of the Council for Responsible Nutrition.

The Council for Responsible Nutrition (CRN) appreciates this opportunity to provide testimony to the Senate Subcommittee on Consumer Protection, Product Safety and Insurance. We want to reassure you and your colleagues, your constituents and our customers that CRN’s members are committed to manufacturing and marketing high quality, safe and beneficial products that have a valuable and appropriate role in weight management regimens. CRN is also committed to ensuring that consumers receive truthful, accurate and non-misleading information about dietary supplements on the label and in advertising.

CRN, founded in 1973 and based in Washington, DC, is the leading trade association representing dietary supplement manufacturers and ingredient suppliers. CRN companies produce a large portion of the dietary supplements and nutritional products marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents nearly 150 companies that manufacture or market dietary

supplements, functional foods and their nutritional ingredients, or supply products and services to those suppliers and manufacturers. Our member companies comply with a host of federal and state regulations governing dietary supplements in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics.

Weight management is a serious issue. According to the 2013 Gallup-Healthways Well-being Index, the number of adults in the U.S. who need to be more conscious of their weight continues to climb: 27 percent are classified as obese, and another 35 percent are considered overweight.¹ At the same time, a Gallup poll from last November indicates that 51 percent of Americans say they want to lose weight, but just under half of them – only 25 percent – say they are seriously trying to lose weight.²

So it's not surprising that these statistics translate into many Americans who are eager to drop a few pounds. We empathize with the many Americans who are vulnerable to false promises for losing weight fast with everything from rubber pants and bracelets, to sprays, creams, exercise gadgets and dietary supplements. Collectively, Americans spend about \$40 billion a year trying to lose weight.³ The Nutrition Business Journal reports that dietary supplements and meal replacements that are formulated for weight loss are a \$5.3 billion industry⁴ in the U.S., only a fraction of the total, but still a significant sum.

Now let's be clear: a number of dietary ingredients in weight loss supplements, when combined with moderate exercise programs and sensible eating, have been shown in well-regarded clinical trials to be safe and effective for weight management. The truth is that many dietary supplements, meal replacement programs and specially formulated foods can be

¹ U.S. Obesity Rate Climbing in 2013, Gallup, Nov. 1, 2013 <http://www.gallup.com/poll/165671/obesity-rate-climbing-2013.aspx>.

² Americans' Desire to Shed Pounds Outweighs Effort, Gallup, Nov. 29, 2013, <http://www.gallup.com/poll/166082/americans-desire-shed-pounds-outweighs-effort.aspx>.

³ Weight Management Trends in the U.S., 2nd ed. (March 15, 2013) <http://www.packagedfacts.com/Weight-Management-Trends-7429799/>.

⁴ Unpublished data from Nutrition Business Journal, provided June 12, 2014.

beneficial as part of a weight management program. They can increase weight loss over diet and exercise alone, and can help people lead more active lifestyles that help to keep the pounds off.

At the same time, however, other products make outrageous claims that promise the weight will fall off without changing what you eat, and without exercise. Some products tout the latest “miracle” ingredients, falsely claim to be “clinically proven” and may not even contain the levels of ingredients they promote. Some scammers trap consumers in fraudulent credit card programs or offer money-back guarantees but become impossible to track down when the product doesn’t work. And that is the reality of the current weight loss market: it is a tale of two industries – with legitimate manufacturers who responsibly produce products that work and make claims for their products within the bounds of the law, and unscrupulous players who prey on desperation and the insatiable desire to be thin, and will say almost anything to make a quick profit. Along with consumers who are duped by false and misleading claims, the responsible supplement industry, who complies with these standards, also stands to lose when unscrupulous marketers take advantage with misleading and unsupported ads.

The Dietary Supplement Health and Education Act (“DSHEA”) requires that all supplements must have substantiation for the claims they make, and that includes weight loss claims. The Food and Drug Administration’s (FDA) regulations establish detailed requirements for what constitutes adequate substantiation for these “structure/function claims,” which are modeled after Federal Trade Commission (FTC) standards for truthful and non-misleading advertising claims. These requirements can be found in the FDA’s “Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act”⁵ and its “Guidance for Industry: Structure/Function Claims, Small Entity Compliance Guide.”⁶ The generally accepted standards for the substantiation of weight management claims include requirements that there must be research on humans showing demonstrable weight loss; that the studies use the same ingredients at the same levels as contained in the products; and that the research shows a statistically significant benefit over placebo in double-blinded, placebo-controlled studies.

⁵ <http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm073200.htm>.

⁶ <http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm103340.htm>.

CRN is also greatly concerned about the ingredients found in some weight loss products that masquerade as dietary supplements for weight loss. Despite their labeling claims of being “all natural” and “completely safe,” some of these products contain prescription drug ingredients and are illegally and erroneously marketed as dietary supplements. FDA has taken enforcement actions with respect to no less than 250 products in the past six years. These products have contained ingredients like sibutramine, a powerful weight loss pharmaceutical ingredient that was removed from the market by FDA for safety reasons. These weight loss products are potentially dangerous to consumers because they may cause side effects or adverse interactions with other drugs, and because the product labeling fails to disclose the presence of these powerful substances, consumers are unaware of their presence. Although FDA has brought civil and criminal actions against some of the marketers of these illegal products, the agency must do more to protect consumers, including working more closely with the U.S. Justice Department to bring criminal charges against those who introduce these dangerous products into the market.

Just as DSHEA calls on FDA to oversee claims made in dietary supplement labeling, the Federal Trade Commission Act authorizes the FTC to enforce the prohibition on false, misleading and deceptive claims made in the advertising of weight loss products. The FTC’s “Dietary Supplements: An Advertising Guide for Industry”⁷ describes in detail how the general principles of the statute apply specifically to the health-related claims made for dietary supplements, namely that advertising claims must be truthful, not misleading and substantiated with credible scientific evidence.

CRN has publicly supported—and will continue to applaud the numerous enforcement actions brought by the FTC in recent years and the more than \$438 million in fines and penalties assessed by the Commission since 2004 against deceptive weight loss advertising. Enforcement sweeps like the FTC’s “Operation Waistline”⁸ and its media awareness programs, like “Gut Check: A Reference Guide for Media on Spotting False Weight Loss Claims,”⁹ help to remove

⁷ <http://business.ftc.gov/documents/bus09-dietary-supplements-advertising-guide-industry>.

⁸ <http://www.ftc.gov/news-events/press-releases/1997/03/ftc-announces-operation-waistline-law-enforcement-and-consumer>.

⁹ <http://www.business.ftc.gov/documents/0492-gut-check-reference-guide-media-spotting-false-weight-loss-claims>.

misleading advertising, and also alert consumers and send a message of deterrence throughout the industry.

For example, FTC's recently released "Gut Check" Guide offers tips for media to help identify weight loss claims that are likely to be too good to be true. It cautions media to review advertising before accepting it because certain claims from advertisers may be a tip-off to deception if the product claims to:

1. cause weight loss of two pounds or more a week for a month or more without dieting or exercise;
2. cause substantial weight loss no matter what or how much the consumer eats;
3. cause permanent weight loss even after the consumer stops using the product;
4. block the absorption of fat or calories to enable consumers to lose substantial weight;
5. safely enables consumers to lose more than three pounds per week for more than four weeks;
6. cause substantial weight loss for all users; or
7. cause substantial weight loss by wearing a product on the body or rubbing it into the skin.

FTC also provides similar tips in its consumer information article "Weighing the Claims in Diet Ads," which warns consumers about ads promising quick and easy weight loss without diet or exercise and what claims are most likely to be untrue.

However, the reality is that in this internet age, along with the proliferation of cable television, talk radio and various online media, and increasing pressures for shrinking ad revenue among print media, both the FTC and FDA have insufficient resources to combat the number of deceptive claims in the market. Some media outlets, eager to accept advertising dollars, turn a blind eye to advertising copy that clearly violates the law. Like the carnival game "whack-a-mole," it seems that every time the FTC targets one company for deceptive advertising, two more pop up. Responsible firms, like CRN's members, suffer along with consumers as legal, reasonable and defensible advertising for weight management gets dwarfed by outlandish claims that violate the law and deceive consumers.

In 2006, CRN began an industry program with the Council of Better Business Bureaus to help self-police the advertising claims of dietary supplement marketers. Over the past seven years, the National Advertising Division (NAD) has conducted almost 200 challenges of the

claims made by supplement marketers, many of which involve weight loss. CRN has committed over \$2 million to underwrite the program at the NAD devoted to the investigation of supplement claims. CRN is proud of the track record this program has for providing fair, thoughtful and transparent decisions, for achieving a high rate of participation with those decisions, and for the precedential effect these decisions have to deter others in the industry from making similarly fraudulent claims.

Almost 20 percent of all the cases the CRN-funded program with the NAD has considered involve claims for weight loss. Commonly recurring problems with these claims include promoting that the ingredients are “clinically proven” or “doctor recommended” when they are neither; claiming clinical research for a product when the study did not examine the same ingredients or ingredients at the same levels as they appear in the product, and test results that are wildly overstated in the advertising. While participation by the advertiser is voluntary, in cases where the advertiser refuses to participate, or where the NAD becomes aware that the advertiser fails to implement the changes recommended in the decision, those cases are referred to the FTC for review and possible legal action.

CRN has also developed a *Roadmap for Retailers*,¹⁰ a six-page brochure to assist those who interact with our consumers, which reminds them that unsupported personal testimonials, promises of cures and treatments, and exaggerated claims that are not supported by the research are both illegal and detrimental to keeping the trust of their customers. CRN also provides “*A Dozen Tips for Consumers*,”¹¹ to help educate the public how to make savvy purchasing decisions. Separately, we have developed guidelines for the industry for the labeling of caffeine content in dietary supplements and functional foods, a common concern especially among weight loss products,¹² and we maintain a Code of Ethics for CRN members.¹³

CRN’s members are committed to manufacturing and marketing high quality, safe and beneficial products. We are likewise committed to ensuring that consumers receive truthful,

¹⁰ <http://www.crnusa.org/roadmap/>.

¹¹ <http://www.crnusa.org/CRNfactsheetconsumertips.html>

¹² <http://www.crnusa.org/caffeine/guidelines.html>.

¹³ http://crnusa.org/who_ssr_code.html.

accurate and non-misleading information on dietary supplements. We believe that the challenge with weight loss products—whether they are dietary supplements, meal programs, clothing or gadgets—is that American consumers’ unrealistic yearnings for a magic bullet align with the temptation for unscrupulous marketers to take advantage of these desires with hollow promises.

Like a successful diet, the solutions are not simple or easy; however, we believe there are four significant steps that can be taken to help address these issues:

1. **Expanding and strengthening voluntary programs among manufacturers and marketers of weight loss products, like our initiative with the NAD.** These self-regulatory programs help consumers identify products that are likely to work and avoid those that aren’t. Third-party certification programs that audit manufacturing practices and test ingredients against label claims can also help responsible marketers to distinguish their products from ones that don’t measure up.
2. **Increasing resources and priorities for the enforcement of existing legal requirements by both the FTC and FDA.** The legal standards for substantiation of claims made in product labeling and advertising, including internet websites, are sufficient to protect consumers while balancing the rights of marketers to make truthful statements about their products and to present emerging science. However, more needs to be done to target bad actors and remove untruthful claims. We urge Congress to provide adequate resources to both FDA and FTC with direction to the agencies to make prosecution of untruthful advertising and labeling a priority.
3. **Calling on media outlets and online retailers to conduct their own advertising review before accepting advertising with claims that are illegal and simply “too good to be true.”** Claims of dramatic weight loss that don’t require any change in diet or exercise, that promise permanent fat reduction or that offer overnight results are inherently suspect. Media outlets, including newspapers, magazines, radio and television stations, internet websites and social media sites, all have a role in helping to prevent consumer fraud. Incentives for these venues to screen advertising and reject ads that are blatantly deceptive must be strengthened.
4. **Educating consumers to be realistic about weight loss strategies and expectations to make them less vulnerable to outrageous and unsupported claims.** When consumers

better understand that meaningful weight loss occurs slowly and steadily, and that so-called “miracle” products are non-existent, unscrupulous marketers will find less demand for their potions and gimmicks.

CRN shares this Committee’s concerns about bad actors in the industry and we denounce false, misleading or deceptive marketing practices—activities engaged in by a few who have damaged the reputation of the responsible industry. We look forward to cooperating with the other witnesses at today’s hearing to develop solutions that strengthen the trust of consumers in dietary supplements.

Thank you for the opportunity to share our views with the Committee.