

BEFORE THE FEDERAL TRADE COMMISSION

In re: International Dairy Foods Association)
 Dairy Management, Inc.)
 National Dairy Council)
 Draft Chicago)
 Lowe & Partners)
 Weber Shandwick)
 The Dannon Company, Inc)
 General Mills, Inc.)
 Kraft Foods Global, Inc.)
 McNeil Nutritionals, LLC)
 Lifeway Foods, Inc.)

Docket No. _____

PETITION TO PROHIBIT FALSE AND MISLEADING ADVERTISING

* * *

Submitted to:

Federal Trade Commission
Consumer Response Center
600 Pennsylvania Ave., NW
Washington, DC 20580

On: April 21, 2005

Submitted by:

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Drink Milk. Lose Weight. Make your weight-loss plan more effective with dairy products. Twenty-four ounces per day of milk, yogurt, or cheese will cause greater weight loss than just cutting calories. Dairy products speed up your metabolism so you will burn more fat. It's not just the calcium—it's all the components of dairy products working together that cause this effect. Eating dairy products will not only take off the pounds more quickly, but it will take those pounds off in the right place: around the waist.

These and other similar false and misleading claims are part of the latest advertising campaign by various dairy trade associations and dairy product manufacturers (the dairy industry). Pursuant to the Federal Trade Commission Act (the FTCA or Act), 15 U.S.C. § 41 et seq. (1980), and 16 C.F.R. § 2.1, the Physicians Committee for Responsible Medicine (PCRM) requests that the Federal Trade Commission (the FTC or Commission) halt these and other false and misleading claims made in print, television, and Internet advertising by the parties named above and any other party engaging in such advertising. These advertisements constitute “false advertisements” as defined by Sections 12 and 15 of the FTCA, 15 U.S.C. §§ 52, 55, and hence are “unfair or deceptive” under Section 5 of the FTCA, 15 U.S.C. § 45, as interpreted by the Commission in its “Policy Statement on Deception,” “Policy Statement on Unfairness,” and “Enforcement Policy Statement for Food Advertising.”

To the extent that the U.S. Department of Agriculture (USDA) and Food and Drug Administration (FDA) have concurrent jurisdiction over the matter, we request that the Commission work with USDA and FDA officials to remedy the concerns raised in this petition.¹

I. INTRODUCTION

A. Summary of the Complaint and Requested Action

PCRM requests the Commission to institute an investigation against the International Dairy Foods Association (IDFA), Dairy Management Inc. (DMI), the National Dairy Council (NDC), The Dannon Company, Inc., General Mills, Inc., Kraft Foods Global, Inc., McNeil Nutritionals, LLC, Lifeway Foods, Inc., the advertising agencies Draft Chicago, Lowe & Partners Worldwide and Weber Shandwick, and any other party engaging in such advertising (hereinafter referred to as “dairy advertisers”), for dissemination of false and misleading advertisements in violation of the FTCA.

In order to take advantage of the societal alarm over America’s growing obesity epidemic, as well as the government’s new relaxed standards allowing food manufacturers to make health claims without substantial scientific agreement, dairy advertisers developed a promotional

¹ In its Memorandum of Understanding with the FDA, the FTC confirmed its commitment to prevent deception of the public and took *primary* responsibility for preventing deceptive food advertising. See Working Agreement Between FTC and FDA, 4 Trade Reg. Rep. (CCH) 9, 850.01 (1971) (emphasis added). To the extent USDA or FDA have primary jurisdiction, PCRM asks that the Commission advise these agencies to take action.

campaign centered around the spurious health claim that consuming dairy products is an effective obesity prevention tool (the “weight loss promotion”). Disguising their purely profit-making motive with an insincere concern for public health, dairy advertisers are duping consumers into believing these bogus health claims. These claims divert people from legitimate and healthy weight loss plans and, once again, consumers are misled into believing there is a magic bullet to weight loss.

This weight loss promotion constitutes deceptive advertising. The claims made by dairy advertisers in myriad print, television, and Internet advertising that consuming a minimum of 24 ounces of dairy products a day can be used as a tool for obesity prevention and will result in better health, greater weight loss, increased breakdown and burning of body fat, and the preservation of muscle tissue compared to a diet comprised of less or no dairy products is false and misleading. They are based on studies performed on mice, thus inconsequential to a human health claim, and on very limited and unconfirmed human studies *that rely on caloric restriction* to show a weight loss. Any food could be substituted for dairy products in this scenario—french fries for example—and there would be a similar weight loss. It is the reduction in calories that causes weight loss, not the dairy products. In fact, human studies in which individuals simply added dairy products to their diet did not result in weight loss. Rather, in the absence of caloric restriction, dairy products have either had no effect at all or have even caused weight gain.

Because the relevant body of research does not support dairy advertisers’ health claims, dairy advertisers have resorted to distortions, exaggerations, and even omissions of integral portions of the relevant science in asserting these claims. Additionally, dairy advertisers have omitted information about the serious health problems caused or aggravated by dairy products, including digestive problems, some cancers, and cardiovascular disease. Therefore, in this petition, PCRM raises critical concerns about dairy advertisers’ stated and implied health claims, as well as the omissions of material facts from the advertisements.

For the foregoing reasons, PCRM requests that the Commission:

- (1) Bring an action pursuant to Section 13 of the FTCA, 15 U.S.C. § 53, to enjoin further dissemination, or causing the dissemination, of the dairy/weight loss advertisements and the claims made therein in any manner whatsoever, pending issuance of a complaint under Section 5 of the FTCA, 15 U.S.C. § 45;
- (2) Initiate action under Section 5 of the Act, 15 U.S.C. § 45, to permanently prohibit the dissemination, or causing the dissemination, of the dairy/weight loss advertisements and the claims made therein;
- (3) Require corrective advertising; and
- (4) Work with officials from USDA and FDA to ensure that USDA and FDA supervised organizations adhere to the laws prohibiting unfair and deceptive advertising.

B. Parties

International Dairy Foods Association (IDFA) is the dairy industry's lobbying arm headquartered at 1250 H Street, NW, Suite 900, Washington, DC 20005. IDFA participated in the development of the weight loss promotion, which it helped launch in October 2003.²

Dairy Management, Inc. (DMI) is a dairy industry trade association headquartered at 10255 West Higgins Road, Suite 900, Rosemont, IL 60018, that promotes demand for U.S. dairy products on behalf of America's dairy farmers. DMI participated in the development of the weight loss promotion, which it helped launch in October 2003.³

The National Dairy Council (NDC) is the nutrition marketing arm of DMI and shares the same office with DMI located at 10255 West Higgins Road, Suite 900, Rosemont, IL, 60018. NDC funded studies relied upon in weight loss promotion and helps promote the consumption of dairy products using these weight loss claims.⁴

The Dannon Company, Inc., sells and produces six million cups of yogurt a day. Dannon participated in the development of the weight loss promotion,⁵ and currently has an advertising campaign to promote the consumption of its Light 'n Fit nonfat yogurt called "Slim Down with Yogurt."⁶

General Mills, Inc., manufactures Yoplait brand yogurt. General Mills participated in the development of the weight loss promotion⁷ and markets Yoplait yogurt using the claim that yogurt consumption results in increased weight and fat loss.⁸

Kraft Foods Global, Inc., is the manufacturer of various dairy products, including cheddar, Colby, Monterey Jack, and mozzarella cheeses, Cracker Barrel cheddar and Swiss cheeses, Velveeta processed cheese spread, Kraft American singles, and Breakstone's sour cream and cottage cheese. Kraft participated in the development of the weight loss promotion⁹ and markets its cheese products using the claim that calcium from dairy products results in increased body fat loss.¹⁰

² See Joint Presentation by IDFA, DMI, and the Milk Processor Education Program on initiating the "Healthy Weight With Dairy" campaign, attached at Exhibit 1, available at http://www.milkpep.org/programs/hwd_exec_briefing.ppt.

³ See 2004 USDA Annual Report to Congress at 9, available at http://www.ams.usda.gov/dairy/prb/prb_rept_2004.htm, and Exhibit 1.

⁴ See Exhibits 1 and 2.

⁵ See Exhibit 1.

⁶ See Exhibit 3, also available at http://www.lightnfit.com/ln/lnstore/cgi-bin/ProdSubEV_Cat_300006_NavRoot_200.htm.

⁷ See Exhibit 1.

⁸ See Exhibit 4, also available at http://www.yoplait.com/health_weightloss.aspx.

⁹ See Exhibit 1.

¹⁰ See Exhibit 5.

McNeil Nutritionals, LLC, is the manufacturer of Lactaid milk and has produced and distributed advertising material for Lactaid using the dairy/weight loss claim.¹¹

Lifeway Foods, Inc., is the manufacturer of Kefir, a probiotic dairy beverage similar in taste and texture to a drink-style yogurt. Lifeway markets Kefir using the dairy/weight loss claim.¹²

Draft Chicago is an advertising agency headquartered at 633 North St. Clair Street, Chicago, IL 60611, that participates in the weight loss promotion.¹³ In particular, Draft Chicago is responsible for the “24/24 Milk your diet. Lose weight!” part of the campaign being executed through the collaboration of several advertising agencies. Draft Chicago created the overall concept and developed all in-store and online promotions for this effort.

Lowe & Partners Worldwide is an advertising agency headquartered at 150 East 42nd Street, New York, New York 10017, that created the advertising for the “24/24 Milk your diet. Lose weight!” part of the weight loss promotion.¹⁴

Weber Shandwick is an advertising agency headquartered at 640 Fifth Avenue, New York, NY 10019, that spearheaded the public relations initiatives for the “24/24 Milk your diet. Lose weight!” part of the weight loss promotion.¹⁵

PCRM is a nonprofit public health advocacy association located at 5100 Wisconsin Avenue, NW, Washington, DC, 20016, supported by more than 100,000 physician and layperson members. PCRM advocates for preventive medicine through good nutrition.

C. Jurisdiction

The FTC has jurisdiction over claims made by corporations, trade associations, and food advertisers pursuant to sections 5, 12, and 15 of the FTCA, which prohibit “persons, partnerships, or corporations” from engaging in “unfair or deceptive acts or practices” and making “any false advertisement” that is “misleading in a material respect.”¹⁶

As IDFA, DMI, and NDC are nonprofit trade associations with a mission to promote the growth and increase the profits of the dairy industry, they are subject to the jurisdiction of the FTC.¹⁷

¹¹ See Exhibit 6.

¹² See Exhibit 7.

¹³ See Exhibit 8, also available at

http://www.draftworldwide.net/Breakingwork/Breakingwork_04/milkpep/.

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ See 15 U.S.C. §§ 45, 52, 55.

¹⁷ See *FTC v. National Commission on Egg Nutrition*, 517 F.2d 485 (1975) (a nonprofit corporation that was organized to promote the general interests of the egg industry is within the jurisdiction of the FTC); *Community Blood Bank of Kansas City Area, Inc. v. FTC*, 405 F.2d 1011, 1022 (8th Cir. 1969) (the definition of “corporation” in the FTC Act includes “nonprofit

The FTC has jurisdiction over Dannon, General Mills, Kraft, McNeil Nutritionals, and Lifeway Foods pursuant to the FTCA’s unambiguous statutory language regarding corporations. Further, advertising agencies are subject to the jurisdiction of the FTC for false and deceptive representations in advertisements concerning the product of the agency’s client.¹⁸

D. Why This Case Is Appropriate for Commission Action

Charged with protecting consumers from false and misleading health information in advertising, the FTC has a long history of aggressively challenging deceptive claims regarding weight loss. Deceptive weight loss claims have a negative effect on public health and distort the competitive marketplace—consumers spend billions of dollars a year based on false promises of weight loss, money wasted when these promises ring hollow. Without FTC intervention, consumers are faced with trying to understand which claims are true and which are not, a virtually impossible task.

The weight loss promotion greatly harms consumers by making false and unsupported health claims, distorting the body of science, and omitting material facts about the negative health effects associated with consuming dairy products. This not only prevents consumers from making informed purchasing decisions, but also actually causes them to make purchasing decisions that may negatively affect both their ability to control their weight and to protect their health.

E. Commission Discretion

The FTC notes that it “pays closest attention to . . . ads that make claims about health” or “ads that make claims that consumers would have trouble evaluating for themselves.”¹⁹ The weight loss promotion advertisements make claims about health designed to engender trust by using celebrity-spokespersons and by claiming to be science-based, claims which are virtually impossible for consumers to evaluate for themselves.

In deciding which cases to bring, the FTC states that it concentrates on national advertising.²⁰ The subject campaign is an ongoing, multi-million dollar national advertising campaign that potentially affects every consumer in the country. The FTC also notes that it focuses on advertisements that “represent a pattern of deception, rather than an individual dispute between a consumer and a business or a dispute between two competitors.”²¹ The weight loss promotion, a national advertising campaign with almost total industry participation, has been active since October 2003. Since that time, print advertisements have run in scores of national magazines, including *People*, *TV Guide*, *Fitness*, and *Health*, trade journals including *Washington Family Physician* and *School Foodservice & Nutrition*, and on broadcast and cable television, including

corporations without shares of capital, such as trade associations, which ‘carry on business for (their) own profit or that of (their) members.’”)

¹⁸ *Colgate-Palmolive Co. v. FTC*, 310 F.2d 89 (1st Cir. 1962).

¹⁹ “Frequently Asked Advertising Questions: A Guide for Small Business,” available at <http://www.ftc.gov/bcp/online/pubs/buspubs/ad-faqs.htm>.

²⁰ *Id.*

²¹ *Id.*

“Dr. Phil,” “Will & Grace,” “Good Morning America,” “Alias,” and various Style Channel programs. The campaign also includes Internet advertising (e.g. www.healthyweightwithdairy.com; www.2424milk.com; www.yoplait.com; www.lightnfit.com; www.kraftfoods.com/dairy; <http://www.lactaid.com>; www.kefir.com). This promotion indisputably represents a pattern of deception aimed at all consumers who are concerned about their health, preventing obesity, maintaining a healthy weight, or losing weight.

Finally, the Commission notes that it considers “[t]he amount of injury - to consumers’ health... or wallets - that could result if consumers rely on the deceptive claim.”²² Inherent in a deceptive weight loss claim is the inevitable injury to consumers’ health. From an economic standpoint, the advertisements are designed to deceive consumers into buying dairy products when they otherwise may not. To the extent the consumer would not buy the product, the campaign costs every purchasing dairy consumer the price of the purchase. According to IDFA, the value of all milk production (which is then used to manufacture all dairy products) in 2003 was \$21.4 billion nationwide.²³ To the extent that even a small percentage of this amount is due to the false health claims that are the subject of this petition, the amount of injury to consumers’ wallets is extensive.

II. BACKGROUND

A. Taking Advantage of the Obesity Epidemic and Relaxed FDA Standards

Americans’ per capita consumption of milk continues to decline, despite the vigorous efforts of the dairy industry to get Americans to consume more milk. In December 2001, the *Surgeon General’s Call to Action to Prevent and Decrease Overweight and Obesity* was released, warning that overweight and obesity have reached epidemic proportions in the United States, with an estimated 61 percent of adults overweight or obese and 13 percent of children and adolescents overweight. The *Call to Action* also cautioned that hundreds of thousands of deaths a year in this country are currently associated with overweight and obesity, which, left unabated, may soon cause as much preventable disease and death as cigarette smoking.²⁴ Since that time, it seems that, more than ever before, everyone has tried to jump on the obesity-prevention bandwagon.

So, not wanting to be left out in the cold, in April 2003, dairy advertisers “Joined Forces to Address the [Obesity] Opportunity,” by holding a “joint strategy meeting.”²⁵ In addition to using the obesity crisis as an impetus for the campaign, the meeting participants also noted that the claim would be more likely to withstand FDA scrutiny because of the FDA’s new relaxed standards for making unproven health claims.²⁶

²² *Id.*

²³ See <http://www.idfa.org/facts/trends.cfm>.

²⁴ See <http://www.surgeongeneral.gov/topics/obesity/calltoaction/toc.htm>.

²⁵ See Exhibit 1.

²⁶ *Id.*

Thus, the “Healthy Weight with Dairy” weight loss promotion was born. This weight loss promotion is a multi-million dollar campaign comprised of many components, including national and regional print, television, and Internet advertising directed towards consumers and trade and health professionals, in-store and online promotions, celebrity spokespersons, distribution of weight loss guides, coupons, prize giveaways, a sweepstakes, and various mini-promotions, including “24/24 Milk your diet. Lose weight!” and “Calcium Weighs In.”

B. Dairy Advertisers’ Claims

Since the weight loss promotion was launched in October 2003, dairy advertisers have run countless print, television, and Internet ads. While these advertisements are slickly worded, the message taken home by a reasonable consumer is clear: *Consuming at least 24 ounces of dairy products every day will cause you to lose weight and body fat based on the special combination of nutrients, including calcium, in dairy products.*

Many of the challenged advertisements are attached hereto as exhibits 2-21. Examples of some of the false and misleading claims contained in these advertisements are listed below:

- “One approach [to losing weight] is getting at least three servings a day of milk, cheese or yogurt instead of some of your current choices.”
- “Getting calcium and protein from lowfat or fat-free milk could help you lose more weight than by just reducing calories.”
- “The Secret’s in the Science.”
- “Calcium in milk is approximately twice as effective as calcium supplements in stopping fat storage and triggering fat breakdown.”
- Increasing consumption of dairy products will reduce the nation’s obesity epidemic.
- “Increasing dairy consumption to just 3-4 servings a day would result in billions of dollars in healthcare cost savings.”
- An advertisement targeting physicians implores: “One approach [to losing weight] is to encourage your patients to include at least 3 servings of milk, cheese, or yogurt as part of a reduced-calorie diet. Simply put, if they change how they look at dairy, they may change how their bodies look.”
- “And milk is the only beverage that naturally provides the unique combination of calcium and protein for healthy, effective weight loss support... So it’s time to add healthy weight loss to the already extensive list of good things that milk can do for your body.”
- “Drink Milk. Lose weight?... [D]rinking 3 glasses of milk daily when dieting may promote the loss of body fat while maintaining more muscle. The calcium and protein in milk may help explain these weight loss benefits.”

Additionally, the advertisements do not always limit the recommendation to lowfat or fat-free dairy products. For instance, the Kelly Preston advertisement states, “Studies show that people

source of calcium. So drink 24 oz. of milk every 24 hours for the calcium you need.”²⁷ Another advertisement boldly suggests “having a latte” for weight loss.²⁸ Kraft announces the “good news” that you can burn more fat by consuming any of its cheese products.²⁹

C. Statutes and Regulations

The FTC Act makes it unlawful to engage in unfair or deceptive commercial practices³⁰ or to induce consumers to purchase certain products through advertising that is misleading in a material respect.³¹ Under the FTC Act, an advertisement is considered deceptive if it contains a representation or omission that is likely to mislead consumers acting reasonably under the circumstances, and that representation or omission is material. A representation may be made by express or implied claims. An express claim directly makes a representation while an implied claim requires an examination of the advertisement’s overall impression. Omission of information can also be deceptive if it leaves consumers with a misimpression about the product. A material representation or omission is one that is likely to affect a consumer’s choice or use of the product. Express claims and claims involving health or safety are presumptively material.³²

The legal framework for Commission action and interpretation of 15 U.S.C. §§ 45, 52, and 55 is set forth in the FTC’s Enforcement Policy Statement on Food Advertising (the FTC Enforcement Policy), which relies on and works in conjunction with

- the Nutrition Labeling and Education Act of 1990 (NLEA)³³
- FDA food labeling regulations implementing the NLEA³⁴
- FTC Policy Regarding Advertising Substantiation (FTC Substantiation Policy)³⁵
- FTC Policy Statement on Deception (FTC Deception Policy)³⁶

The NLEA authorizes FDA to regulate food labels and was designed to give consumers more scientifically valid information about the foods they eat. Among other things, the NLEA authorizes FDA to allow health claims—statements that describe the relationship between a

²⁷ See Exhibit 11.

²⁸ See Exhibit 21.

²⁹ See Exhibit 5.

³⁰ 15 U.S.C. § 45.

³¹ *Id.* at §§ 52, 55.

³² FTC Deception Policy.

³³ Pub. L. No. 101-535, 104 Stat. 2353 (codified in part at 21 U.S.C. § 343(i), (q), and (r)).

³⁴ For instance, FDA regulates nutrient content claims, 21 CFR § 101.69(b), and health claims, 21 CFR § 101.14.

³⁵ 48 Fed. Reg. 10,471 (1984), *reprinted in Thompson Medical Co.*, 104 F.T.C. 648, 839 (1984), *aff’d*, 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987); *see* <http://www.ftc.gov/bcp/guides/ad3subst.htm>.

³⁶ *See Cliffdale Associates, Inc.*, 103 F.T.C. 110, 176 (1984), reprinted as appendix letter dated Oct. 14, 1983, from the Commission to The Honorable John D. Dingell, Chairman, Committee on Energy and Commerce, U.S. House of Representatives (Deception Statement); *see* <http://www.ftc.gov/bcp/policystmt/ad-decept.htm>.

nutrient and a disease or health-related condition—on food labels. In order for any health claim to be permitted on a food label, food companies must petition the FDA, which, until recently, could only approve the use of health claims that were supported by “significant scientific agreement” among experts.³⁷ The “significant scientific agreement” standard is based on a body of sound and relevant scientific data and is intended to provide a high level of confidence that the validity of the diet/disease relationship is not likely to be reversed by new and evolving science. These “unqualified” health claims require significant scientific agreement based on the totality of publicly available scientific evidence.

Recently, the FDA issued interim regulatory guidance³⁸ allowing lower standards of proof for the substantiation of substance/disease relationships that are the subject of “qualified” health claims.³⁹ In particular, under the “Consumer Health Information for Better Nutrition Initiative,” the FDA issued “Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements” and “Interim Evidence-based Ranking System for Scientific Data.” Pursuant to this guidance, qualified health claims language must be worded (“qualified”) in such a way that consumers are not misled about the nature of the supporting science. Qualified health claims must still be pre-approved by FDA.

Additionally, FDA regulations recognize that the consumption of fat, saturated fat, cholesterol, and sodium are associated with an increased risk of certain diseases and health-related conditions, particularly cancer, cardiovascular disease, and hypertension.⁴⁰ Thus, FDA regulations prohibit any health claim on the labels of foods that contain a pre-established level of total fat, saturated fat, cholesterol, or sodium.⁴¹ For instance, if a food has more than 13 grams of fat, 4 grams of saturated fat, or 60 milligrams of cholesterol per serving, no health claim can be made on the label of that food product.⁴²

Relying on these FDA regulations, FTC’s Enforcement Policy provides guidance with respect to the use of health claims in food advertising. For instance, FTC standards for the substantiation of health claims in food advertising share many elements with FDA’s approach to such claims in food labeling. In particular, the Commission imposes a rigorous substantiation standard, looking to “well-designed studies, including clinical research and other forms of reliable and probative scientific evidence.” The Commission evaluates substantiation in the context of the surrounding

³⁷ 21 U.S.C. § 343; 21 CFR § 101.14.

³⁸ While these interim guidelines are not legally enforceable because they have not been promulgated through notice-and-comment rulemaking, they do set forth the Agency’s intended course of action for regulations. As of this date, FDA has not issued proposed or final regulations on this subject, but did issue an Advanced Notice of Proposed Rulemaking on Nov. 25, 2003. *See* 68 Fed. Reg. 66040.

³⁹ FDA adopted this policy to respond to court rulings establishing that consumers have a First Amendment right to truthful health information even if that information is not supported by significant scientific agreement. *See Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999); *Whitaker v. Thompson*, 248 F. Supp. 2d 1 (D.D.C. 2002).

⁴⁰ 21 CFR §§ 101.73-101.75.

⁴¹ 21 CFR § 101.14(a)(4).

⁴² *Id.*

body of evidence and does not look to isolated studies, especially if those studies are unrepresentative of the larger body of evidence.

Using the same criteria, the Commission will likely reach the same conclusion as FDA as to whether an unqualified health claim is adequately supported by the scientific evidence. As part of this analysis, the Commission will also give significant weight as to whether FDA has considered and approved or denied a health claim. “The absence of an FDA determination that a health claim is scientifically valid will be a significant factor in the Commission’s assessment of substantiation for the claim.” As to health claims that have not been approved by FDA, the Commission requires that they be carefully qualified to convey clearly and fully the extent of the scientific support. “Qualified [health] claims based on evidence that is inconsistent with the larger body of evidence have the potential to mislead consumers and, therefore, are likely to violate Section 5.”⁴³

When a health claim in advertising is made for a food that contains more than the FDA-pre-determined levels of fat, saturated fat, cholesterol, or sodium, FTC is obligated to scrutinize such health claim to ensure the claim is truthful and adequately qualified. For example, to prevent deception, the advertisement should include a disclosure that conveys the presence and significance of the risk-increasing nutrient.⁴⁴

III. ARGUMENT

A. Approval for the Dairy/Weight Loss-Obesity Prevention Health Claims Has Not Been Sought or Obtained

Dairy advertisers basically make two obesity-prevention claims: that the consumption of dairy products will cause *weight* loss and that the consumption of dairy products will cause *fat* loss. These claims are “health claims” that have not been approved by FDA.

“Health claims” characterize the relationship between a substance and its ability to reduce the risk of a disease or health-related condition.⁴⁵ A “substance” means a specific food or component of food.⁴⁶ “Disease” or “health-related condition” means damage to an organ, part, structure, or system of the body such that it does not function properly or a state of health leading to such dysfunctioning.⁴⁷

Milk, cheese, and yogurt are “substances” because they are specific foods. Calcium and protein are also “substances” because they are components of milk, cheese, and yogurt. Moreover, obesity is a disease and a health-related condition. Recently, the IRS began recognizing obesity as a disease,⁴⁸ and Medicare redefined obesity as an illness.⁴⁹ The *Surgeon General’s Call To*

⁴³ FTC Enforcement Policy.

⁴⁴ *Id.*

⁴⁵ 21 CFR § 101.14.

⁴⁶ *Id.* at 101.14(a)(2).

⁴⁷ *Id.* at 101.14(a)(5).

⁴⁸ *See* IRS Publication 502.

Action To Prevent and Decrease Overweight and Obesity noted that the health consequences of overweight and obesity is “a public health issue that is among the most burdensome faced by the Nation... This burden manifests itself in premature death and disability, in health care costs, in lost productivity, and in social stigmatization. The burden is not trivial. Studies show that the risk of death rises with increasing weight. Even moderate weight excess...increases the risk of death.” Moreover, the Surgeon General noted, overweight and obesity are associated with premature death, type 2 diabetes, heart disease, stroke, hypertension, gallbladder disease, osteoarthritis, sleep apnea, asthma, breathing problems, and cancer (endometrial, colon, kidney, gallbladder, and postmenopausal breast), among other health dysfunctions.⁵⁰

Thus, the dairy/weight and fat loss claims are health claims that must be approved by FDA through the petition process. However, FDA has not authorized as unqualified or qualified health claims either of the claims that dairy calcium—or for that matter, calcium—is associated with a greater likelihood of weight loss or fat loss, nor has the dairy industry petitioned FDA for either a qualified or unqualified health claim related to the dairy/weight and fat loss hypothesis.⁵¹ Even if the dairy industry had petitioned for approval to make these health claims, FDA would undoubtedly have denied such petition because the scientific evidence in support of each of these claims would fail to meet even the lowest standard set forth by FDA.⁵² Factoring in the failure of dairy advertisers to seek approval before making these health claims, the absence of an FDA determination that these claims are scientifically valid, and the absolute lack of reliable scientific support for these claims, the Commission must find that the dissemination of all of these advertisements is in violation of Section 5 of the FTCA.

Moreover, even if FTC were to find that the subject claims are not “health claims,” but are instead structure/function claims⁵³ or dietary guidance,⁵⁴ which are not subject to FDA pre-review or pre-authorization, the claims are still deceptive because they are false and misleading.⁵⁵

⁴⁹ <http://www.washingtontimes.com/business/20040715-104805-1408r.htm>.

⁵⁰ http://www.surgeongeneral.gov/topics/obesity/calltoaction/1_2.htm.

⁵¹ This conclusion is based on a review of FDA’s Web site that lists all petitions submitted for approval of both unqualified and qualified health claims, available at <http://www.cfsan.fda.gov/~dms/lab-qhc.html#petition>.

⁵² See Interim Evidence-Based Ranking System for Scientific Data.

⁵³ A structure/function claim describes the effect that a substance has on the structure or function of the body and does not make reference to a disease (e.g., “calcium builds strong bones”). See <http://www.cfsan.fda.gov/~dms/hclaims.html>.

⁵⁴ “Dietary guidance” contains one element or another—a substance or a disease—but not both (e.g., diets rich in fruits and vegetables may reduce the risk of some types of *cancer*” or “*carrots* are good for your health”). 58 Fed. Reg. 2478 at 2487 (January 6, 1993).

⁵⁵ FTC Deception Policy.

B. Some of the Recommended Dairy Products Have Disqualifying Nutrient Levels

As set forth above, FDA regulations disqualify making a health claim on food labels for foods with more than 13 grams of fat, 4 grams of saturated fat, or 60 milligrams of cholesterol per serving. Pursuant to FTC's Enforcement Policy, when a health claim is made in an advertisement for a food that contains more than any of these pre-determined nutrient levels, the FTC will scrutinize such health claim to ensure the claim is truthful and adequately qualified. "For example, a health claim describing the benefits of calcium in reducing the risk of osteoporosis, when made in advertising for a dairy product that is high in saturated fat, may create the deceptive impression among reasonable consumers that consuming the dairy product will reduce the risk of osteoporosis without increasing the risk of any other health-related condition or disease, for example, heart disease." To prevent deception, the health claim should include a disclosure that conveys the presence and significance of the risk-increasing nutrient.

The advertisements that do not recommend the consumption of lowfat or fat-free varieties are making a health claim for full-fat dairy products. Whole milk has 5.1 grams of saturated fat per serving. One serving of cottage cheese (1½ c.) has more than 14 grams of fat, almost 9 of them saturated. The smallest Starbucks latte, which is 12 ounces, has 7 grams of saturated fat. One serving of original-flavored Kefir has 5 grams of saturated fat. One serving of Cracker Barrel extra sharp cheddar cheese (1 oz) has 7 grams of saturated fat. One serving of Cracker Barrel Swiss cheese (1 oz.) has 6 grams of saturated fat. One serving of vanilla ice cream (½ c.) has 5 grams of saturated fat.

Accordingly, these and other dairy products bearing the dairy/weight or fat loss health claims contain disqualifying levels of fat and saturated fat. Yet the advertisements fail to disclose the high levels of fat and saturated fat in the products or their relation to cancer and heart disease. Without these disclosures, the stated and implied health claims that dairy consumption can result in weight or fat loss without increasing the risk of any other health-related condition are clearly false and misleading, in violation of the FTC Act.

C. The Body of Scientific Evidence Does Not Support the Claim That Dairy Products Reduce the Risk of Obesity or Cause Greater Weight Loss Than Just Cutting Calories Alone

Dairy advertisers attempt to persuade consumers that dairy products facilitate weight control, citing what they characterize as "a growing body of research" that they assert supports this claim. The body of scientific evidence, including emerging science, however, supports precisely the opposite conclusion: Studies show that adding dairy products to the diet does nothing whatsoever for weight control; in some cases, it encourages weight *gain*.

Dairy advertisers rest their claim on the findings of a single industry-funded experimenter, whose studies are small, poorly controlled, and reported with only minimal detail, yielding inconsistent results. This researcher, Michael Zemel, Ph.D., of the University of Tennessee, Knoxville, consistently fails to report the calorie intake of research participants, making it impossible to assess whether differences in caloric intake alone are responsible for any changes

in weight. Some of his reports are abstracts only, rather than full reports, making it impossible to fully assess his methods or data set. Dr. Zemel has had a financial stake in the outcome of these studies. Not only did he receive grants from the National Dairy Council and the breakfast cereal and yogurt industries to do his studies,⁵⁶ but he also holds a patent with the U.S. Patent and Trademark Office to the method of using calcium and/or dairy products for the treatment and prevention of obesity.⁵⁷

Dr. Zemel's findings supporting dairy advertisers' claims have not been replicated by other researchers using similar methods and are not representative of the body of research. Even some of Dr. Zemel's results are contrary to the advertisers' claims, showing that dairy product consumption does not facilitate weight loss.

The following is a summary of the body of science evaluating the question of whether dairy product consumption, either with or without a reduction in energy intake, will prevent obesity or facilitate weight loss.⁵⁸ Scientific studies have tested the effect of dairy product or calcium supplement consumption on body weight in both the presence and absence of calorie restrictions, and these studies are described below. In either case, the evidence fails to show or lend support to the claim that dairy product or calcium consumption improves weight control or results in weight or fat loss.

1. Clinical Studies on Dairy Products or Calcium Supplements without Energy Restriction

Barr (2003)⁵⁹ of the University of British Columbia reviewed the scientific literature on the effect of dairy products or calcium supplements on bone health. These studies also adduced findings on body weight. Of 26 studies reviewed, nine involved dairy products and 17 involved calcium supplements.

Of the nine dairy trials, two showed an *increase* in body weight in the dairy groups, compared to the non-dairy groups, while seven showed no difference in body weight (including BMI) or adiposity. None showed any weight improvement whatsoever.

In the 17 calcium supplementation trials, 16 showed that changes in body weight or body fat (where noted) were similar between the calcium-supplemented and the unsupplemented control groups. Only one study found greater weight loss in the calcium-supplemented group. This trial did not use dairy products as the treatment.

⁵⁶ See <http://www.cspinet.org/integrity/>.

⁵⁷ See Zemel patent information, attached as Exhibit 22.

⁵⁸ Note that the first time a study is identified in the body of this petition, it will be presented in bold; if it is referenced again, it will be in unbolded text.

⁵⁹ Barr SI. *Increased dairy product or calcium intake: Is body weight or composition affected in humans?* J Nutr. 2003;133:245S-248S.

Of these 26 studies, ten adduced data on body fat. Of these, none showed any difference in body fat change between high-dairy or high-calcium treatment groups and the untreated or low-dairy-consuming control groups.

After the publication of Dr. Barr's review, three additional studies addressed the effect of dairy or calcium on body weight. None reported an effect of dairy or calcium intake on body weight or body fat in the absence of caloric restriction. These studies are described below:

Wosje (2004)⁶⁰ studied the effect of calcium supplementation on weight and body fat in lactating and non-lactating women post-partum. Like the 26 studies reviewed by Barr, Wosje reported that supplementation with one gram/day of calcium did not promote weight or fat loss.

Lappe (2004)⁶¹ tested the effect of dairy products on body weight in 59 pubertal girls who were assigned to either high-dairy or usual dairy intake diets and were followed for two years. Because gradual weight gain is normal during childhood and adolescence, the study helped address the question of whether the addition of dairy products has any ability to prevent obesity or excessive weight gain. The study showed that the girls in the two groups gained weight at the same rate, contradicting the claim that dairy products lead to weight control or play any role in determining fat deposition.

Dairy advertisers cite this study in their supporting materials, even though it does not bolster the dairy/weight loss claim, giving the misleading impression that there is more supporting science than there actually is.⁶²

Gunther (2005)⁶³ assessed the effects of dairy products on weight in nonobese women (women more than 20 percent overweight were excluded). In the one-year study, participants were assigned to one of three groups: (1) a control group that maintained its usual diet, (2) a medium-dairy group consuming 1000-1100 mg of calcium daily, or (3) a high-dairy group consuming 1300-1400 mg of calcium daily. Participants in the two dairy groups were instructed to compensate for the addition of dairy products by reducing consumption of other foods so as to keep their energy intake unchanged. None of the groups lost weight. In fact, the high-dairy group gained 1.5 kg (3.3 lb) over the year, which was slightly (although not statistically significantly) greater than the weight gain in the control group (0.8 kg, 1.8 lb) and the medium-dairy group (0.7 kg, 1.5 lb).

The high-dairy group also gained more body fat, on average, than the other groups (0.5 kg fat gain in the high-dairy group, compared to a 0.3 kg fat gain in the medium-dairy group, and a 0.5 kg fat loss in the control group), although the differences were not statistically significant.

⁶⁰ Wosje KS, Kalkwarf HJ. *Lactation, weaning, and calcium supplementation: effects on body composition in postpartum women.* Am J Clin Nutr. 2004;80:423-429.

⁶¹ Lappe JM, Rafferty KA, Davies M, Lypaczewski G. *Girls on a high-calcium diet gain weight at the same rate as girls on a normal diet: a pilot study.* J Am Diet Assoc. 2004;104:1361-1367.

⁶² <http://www.nationaldairycouncil.org/nationaldairycouncil/healthyweight/science>.

⁶³ Gunther CW, Legowski PA, Lyle RM, et al. *Dairy products do not lead to alterations in body weight or fat mass in young women in a 1-y intervention.* Am J Clin Nutr 2005;81:751-6.

Dairy products clearly did not facilitate weight loss. In fact, if the high-dairy group's experience continued in a similar fashion over a ten-year period, the average group member would have had a 15-kg (33-lb) weight gain, from the average baseline weight of 62.4 kg (137 lb) to 77.4 kg (170 lb), leading to an average body mass index of 27.8, which puts the group well into the overweight range (BMI > 25). The control group's 10-year experience, if similar to the one-year result, would have been a gain of about half as much weight as the high-dairy group.

This study is particularly relevant, because the researchers asked the participants to add dairy products and, simultaneously, to watch their caloric intake. Specifically, participants were asked to reduce consumption of nondairy foods, which is similar to the message consumers may glean from some of the advertisements in question.

Recently, **Huang (2005)**⁶⁴ reviewed both clinical and observational evidence linking dairy intake and obesity in children and adolescents, noting that “collectively, findings across studies fail to demonstrate compellingly a beneficial effect of dairy intake [on body weight or metabolic health] in children and adolescents.” Reviewing evidence on body weight in these age groups, they noted, “all of the intervention studies to date have not shown any effect of dairy.” Further, the authors pointed out that, although some previous authors have hypothesized that dairy consumption might influence body weight or fatness based on findings of some observational studies, such observations may be attributable to lack of control of confounding variables, such as total calorie intake and sweetened beverage intake.

In summary, no scientific studies support the existence of any weight-loss benefit from the addition of dairy products to the diet in the absence of a calorie restriction. One study, conducted by Dr. Zemel and described below, suggested that, in his participant sample, body fat was lost with milk supplementation without caloric restriction, despite the absence of any effect on body weight. No studies have corroborated this finding.

2. Studies on Dairy Products or Calcium Supplements with Energy Restriction

Six studies have examined the question of whether dairy products or calcium supplements facilitate weight loss in the context of a reduced-calorie diet (five studied dairy products; one used calcium supplements). These studies are described below. Because dairy advertisers have based their claim primarily on Dr. Zemel's research, which has financial ties to the industries involved and has serious methodological problems, we will give special consideration to his studies.

Three of these studies were not conducted by Dr. Zemel (Harvey-Berino (2004), Bowen (2004), and Jensen (2001)). None showed any effect of dairy products or calcium supplements on body weight.

⁶⁴ Huang TTK, McCrory MA. *Dairy intake, obesity, and metabolic health in children and adolescents: knowledge and gaps*. Nutrition Reviews 2005;63:71-80.

Harvey-Berino (2004)⁶⁵ In a six-month study at the University of Vermont, 45 participants were randomly assigned to either a high- or low-dairy diet along with a daily energy restriction of 500 calories. There was no difference between the groups for changes in either body weight or body fat.

Bowen (2004)⁶⁶ This randomized, controlled trial assigned 50 overweight adults to energy-restricted diets that were either high in dairy products or low in dairy products. The study's primary aim was to investigate the effect of dairy-containing foods on bone mineral loss during dieting, but it also measured body weight and body fat, finding no difference in weight loss between the groups.

Jensen (2001)⁶⁷ Sixty-two women on a reduced-calorie formula diet were randomly assigned to receive either a calcium supplement or no supplement for three months. The calcium-supplemented group did not lose as much weight as the unsupplemented group (3.1 kg for the calcium-supplemented group, compared to 3.3 kg for the unsupplemented group). This difference was not statistically significant.

In summary, these three studies found no statistically significant effect of dairy products or calcium supplements on body weight or, when measured, body fat.

3. Dr. Zemel's Reports

Dr. Zemel conducted four human clinical studies. They are addressed separately because they have methodological problems and have yielded aberrant results upon which the dairy advertisers are basing their claims.

One of Dr. Zemel's studies used dairy products without caloric restriction and showed no effect on body weight. Three used both dairy product supplementation and caloric restriction, of which one failed to show any significant weight loss related to dairy use, while two others did show weight loss. Each of these studies suffers from the following serious technical problems:

- These studies fail to report on or to control for the main variable that may confound their results, which is caloric intake. This is important, because the most likely reason for weight loss is a reduction in energy intake. So if one group of participants in a study loses more weight compared to other groups, it is essential to know whether these participants cut their calories to a greater degree than the comparison groups. If so, a calorie reduction, not dairy consumption, is the likely reason for any observed weight loss.

⁶⁵ Harvey-Berino J, Gold BC, Lauber R. *The impact of dairy product consumption on weight loss*. Abstract presented at NAASO conference, November 2004.

⁶⁶ Bowen J, Noakes M, Clifton PM. *A high dairy protein, high-calcium diet minimizes bone turnover in overweight adults during weight loss*. J Nutr. 2004;134:568-573.

⁶⁷ Jensen LB, Kollerup G, Quaade F, Sorensen OH. *Bone mineral changes in obese women during a moderate weight loss with and without calcium supplementation*. J Bone Miner Res. 2001;16:141-147.

However, in none of these studies does Dr. Zemel report the degree to which participants actually reduced their calorie intakes.

- These studies do not describe the method by which energy intake was assessed, except to say that Dr. Zemel used “diet diaries.” Normally, a research report would describe the type of record and how the records were analyzed. This failure adds to the difficulty in assessing the control of the primary confounding variable (energy intake) and makes it difficult for others to replicate his research.
- Two of the four studies have not been published except in abstract form, and their methods have not been described except in cursory form.

Each of these is described below. The first used no caloric restriction; the three subsequent reports used energy-restricted diets.

Zemel (2002)⁶⁸ (Abstract only): No significant weight loss. Dr. Zemel reported the results of a trial that involved increasing dairy intake in 34 obese African-American adults (gender was not specified) with no change in caloric intake for 24 weeks. When this high-dairy treatment (3 servings/day) was compared to a low-dairy treatment (<1 serving/day), neither group lost weight. This result contradicts the advertising claim in question. Nonetheless, Dr. Zemel claimed that, despite the absence of any weight loss, the high-dairy group lost 5.4 percent of its body fat, while the low-dairy group lost 0.4 percent of its body fat. These changes were not compared for statistical significance (a standard statistical procedure that tests whether the findings could simply be due to chance) in the study abstract, and he has not yet released any further details of the study.

Of the three studies using calorie restriction, one (Zemel 2004a) showed no statistically significant reduction in body weight. Two (Zemel 2004b, Zemel 2005) reported statistically significant effects of dairy intake on body weight, but both had serious methodological problems, as noted above.

Zemel (2004a)⁶⁹ (Abstract only): No significant difference in weight loss. In this trial, 105 obese subjects were divided into three treatment groups—high-dairy, calcium-supplemented, and low-dairy—and asked to maintain these diets for 12 weeks, along with a calorie-restricted diet. Dr. Zemel excluded 35 percent of the participants from the analysis due to noncompliance. For the 68 participants who met compliance criteria and were included in the analysis (the number of subjects per group was not reported), the difference in weight lost between the different groups was not statistically significant. Weight loss was 4.7 kg in the high-dairy group, 3.0 kg in the low-calcium group, and 2.3 kg in the high-calcium group. Although these findings are not statistically significant, it is noteworthy that the low-calcium group seemingly lost more weight than the high-calcium group, contradicting the hypothesis that calcium facilitates weight loss.

⁶⁸ Zemel MB, et al. *Increasing dairy calcium intake reduces adiposity in obese African-American adults*. *Circulation*. 2002; 106 (suppl 2) II-610. Abstract.

⁶⁹ Zemel MB, Teegarden D, Van Loan M, et al. *Role of dairy products in modulation of weight and fat loss: A multi-center trial*. *FASEB J*. 2004;18:A845.

Those in the high-dairy group reportedly lost more fat (4.4 kg) than those in the low-calcium (2.7 kg) or high-calcium (2.2 kg) groups).

Zemel (2004b)⁷⁰ Zemel reported on the weight lost over 24 weeks by 32 obese individuals assigned to three different calorie-restricted diets: low-dairy/low calcium, high-dairy/high-calcium, and low-dairy/high-calcium. All participants were instructed to restrict daily caloric intake by 500 calories. Average weight loss was 6.6 kg for the low-dairy/low-calcium group, 11.07 kg for the high-dairy/high-calcium group, and 8.6 kg for the low-dairy/high-calcium group. Average body fat loss was 4.8 kg for the low-dairy/low-calcium group, 7.2 kg for the high-dairy/high-calcium group, and 5.6 kg for the low-dairy/high-calcium group.

Like all of Zemel's studies, this study is severely flawed by the failure to report the caloric intake of the participants and how it might have changed during the study, since a change in caloric intake is the most likely reason for weight change. The weight loss of the high-dairy/high-calcium group, about one pound per week, is consistent with what is expected when a dieter reduces caloric intake by 500 calories per day.⁷¹ The low-dairy/low-calcium and low-dairy/high-calcium groups lost on average about one-half pound per week, which is lower than would have been expected if the subjects actually maintained a 500-calorie/day deficit. These findings suggest that differences in weight loss may have been due, not to dairy use, but to differences in caloric intake. Nothing in Dr. Zemel's reported data would contradict such an interpretation.

Zemel (2005)⁷² In this 12-week study, 34 obese adults were assigned to either an experimental weight-loss diet including 1100 mg of calcium per day contributed by yogurt or to a diet that was generally similar, but limited calcium to 500 mg per day. The experimental group lost, on average, 6.6 kg, compared to 5.0 kg in the control group (Zemel reported a P-value of "< 0.01", meaning there is less than a one-in-100 chance that the observed weight-loss difference is due to chance; this statistical finding cannot be verified). The loss of body fat was also reportedly greater in the experimental group. As in Zemel's other trials, the change in caloric intake of participants is not reported. This fact makes it impossible to discount the most likely reason for weight or fat loss—a reduction in calories having nothing to do with the consumption of dairy products.

⁷⁰ Zemel MB, Thompson W, Milstead A, Morris K, Campbell P. *Calcium and dairy acceleration of weight and fat loss during energy restriction in obese adults*. *Obes Res*. 2004;12:582-590.

⁷¹ Groff JL, Gropper SS, Hunt SM. *Advanced Nutrition and Human Metabolism*, 2nd edition. West Publishing Company, St. Paul, Minnesota, 1995.

⁷² Zemel MB, Richards J, Mathis S, Milstead A, Gebhardt L, Silva E. *Dairy augmentation of total and central fat loss in obese subjects*. *Int J Obes*. 2005;29:391-397.

4. Observational Studies⁷³

Observational studies have been conducted on the associations between calcium or dairy products and body weight and/or adiposity. None of these observational studies has shown any association between dairy or calcium intake and weight or fat loss. Indeed, none has observed weight or fat loss at all. Some have observed associations with reduced rate of weight gain or with lower weight or adiposity at a single time point for some participant subgroups, but none supports the dairy advertisers' claim that dairy products will in any way facilitate weight or body fat loss.

It should be noted that, while observational studies play an important role in the research process, they are not designed to show cause and effect and are subject to confounding. For example, some people consume dairy products because they are trying to adhere to what they believe is a healthful diet. These same individuals also tend to follow recommendations regarding reducing fat consumption, increasing fruits and vegetables in the diet, eating fiber-rich foods, and getting regular exercise, making it difficult to assess the role of dairy products or calcium in this context. For that purpose, randomized clinical trials are more helpful.

The demonstration of a weight-reducing effect of dairy products in prospective observational studies, had such a finding ever been adduced, would have been helpful for the dairy advertisers' claim, but still would not be sufficient to establish such a claim. To illustrate this point, we recall the evolution of research data on hormone replacement therapy. In observational studies, estrogen/progesterone preparations were associated with reduced risk of heart disease. However, researchers feared that this association may not have been due to the hormones, but rather to the fact that women taking hormones were generally more health-conscious than other women and may have been more likely to adhere to healthful medical and lifestyle practices. So large randomized clinical trials were conducted, and they showed that, in fact, estrogen/progesterone combinations caused an *increased* risk of heart disease.

A similar situation exists regarding the use of dairy products or calcium supplements in relation to body weight. Because these products have been heavily promoted for their supposed health benefits, prospective observational health studies are affected by the fact that individuals using these products are more likely to be health-conscious, compared to those who are not. This does not discount the value of prospective studies, but clearly limits their interpretation.

To date, nine observational studies investigating the relationship between calcium or dairy intake and body weight have been published in report form (as opposed to abstract form). None of these studies showed weight loss over time in any population group. Of five studies conducted with

⁷³ Observational research is non-experimental research. Observational studies may be based on documentation in archived health records or patient databases maintained by states, insurers, departments or researchers, or may be created prospectively. In these kinds of studies, it is not possible to determine a cause-effect relationship because the researcher does not control the variables. It might be possible to find correlations between observed variables, but this does not indicate the direction of a cause. See <http://web.isp.cz/jcrane/IB/Observations.html>.

adults, three (**Lovejoy (2001)**⁷⁴, **Loos (2003)**⁷⁵, **Jacqmain (2003)**⁷⁶) reported no relationship between calcium or dairy products and body weight in some subpopulations and an inverse relationship in others, one (**Mirmiran (2005)**⁷⁷) reported an inverse relationship between dairy consumption and body mass index, and the fifth (**Lin (2000)**⁷⁸) observed a smaller weight gain in those consuming more dietary calcium. Two studies in adolescents (**Phillips (2003)**⁷⁹, **Novotny (2004)**⁸⁰) showed no relationship between dairy intake or dietary calcium and body weight, while two studies in children (**Barba (2005)**⁸¹, **Tanasescu (2000)**⁸²) showed an inverse relationship between these two factors.

Of eight studies relating calcium or dairy intake to body fat (as opposed to body weight) in adults, adolescents, and children, four (Lin (2000), Novotny (2004), **Carruth (2001)**⁸³, **Skinner (2003)**⁸⁴) observed an inverse relationship, three (Lovejoy (2001), Loos (2003), Jacqmain (2003)) showed an inverse relationship with some subpopulations, but no relationship with others, and one observed no relationship (Phillips (2003)).

As noted above, in none of these observational studies was dairy or calcium intake associated with weight or fat loss, and none supports the dairy advertisers' claim that dairy consumption facilitates weight or fat loss. Rather, associations, when observed in observational studies, were

⁷⁴ Lovejoy JC, Champagne CM, Smith SR, de Jonge L, Xie H. *Ethnic differences in dietary intakes, physical activity, and energy expenditure in middle-aged, premenopausal women: the Healthy Transitions Study*. Am J Clin Nutr. 2001;74:90-95.

⁷⁵ Loos R, Rankinen T, Leon A, et al. *Calcium intake and body composition in the HERITAGE Family Study*. Obes Res. 2003;11(S):597-P.

⁷⁶ Jacqmain M, Doucet E, Despres JP, Bouchard C, Tremblay A. *Calcium intake, body composition, and lipoprotein-lipid concentrations in adults*. Am J Clin Nutr. 2003;77:1448-1452.

⁷⁷ Mirmiran P, Esmailzadeh A, Aziz F. *Dairy consumption and body mass index: an inverse relationship*. Int J Obesity. 2005;29:115-21.

⁷⁸ Lin YC, Lyle RM, McCabe LD, McCabe GP, Weaver CM, Teegarden D. *Dairy calcium is related to changes in body composition during a two-year exercise intervention in young women*. J Am Coll Nutr. 2000;19:754-760.

⁷⁹ Phillips SM, Bandini LG, Cry H, Colclough-Douglas S, Naumova E, Must A. *Dairy food consumption and body weight and fatness studied longitudinally over the adolescent period*. Int J Obes. 2003;27:1106-1113.

⁸⁰ Novotny R, Daida YG, Acharya S, Grove JS, Vogt TM. *Dairy intake is associated with lower body fat and soda intake with greater weight in adolescent girls*. J Nutr. 2004;134:1905-1909.

⁸¹ Barba G, Troiano E, Russo P, Venezia A, Siani A. *Inverse association between body mass and frequency of milk consumption in children*. Brit J Nutr. 2005;93:15-19.

⁸² Tanasescu M, Ferris AM, Himmelgreen DA, Rodriguez N, Perez-Escamilla R. *Biobehavioral factors are associated with obesity in Puerto Rican children*. J Nutr. 2000;130:1734-1742.

⁸³ Carruth BR, Skinner JD. *The role of dietary calcium and other nutrients in moderating body fat in preschool children*. Int J Obes. 2001;25:559-66.

⁸⁴ Skinner JD, et al. *Longitudinal calcium intake is negatively related to children's body fat indexes*. J Am Diet Assoc. 2003;103:1626-31.

with lower weight and body fat at a single point in time or with reduced rate of weight or body fat gain only.

5. Summary of Research Findings

In summary, the body of scientific research contradicts dairy advertisers' claims. Nearly all studies that have investigated an effect of dairy product consumption on weight change over time have found that dairy consumption either increases body weight or has no effect.

Of the 29 clinical trials not using a caloric restriction that were not conducted by Dr. Zemel—26 studies reviewed by Barr and three studies published subsequent to her review—28 showed no effect on body weight. Only one (using calcium supplements, rather than dairy products) suggested any effect on body weight. No studies showed any effect on body fat.

Of the three randomized clinical trials not conducted by Dr. Zemel using a calorie restriction along with dairy products or calcium supplements, none showed any effect on body weight or body fat.

Only one researcher—who has a financial stake in the outcome—showed a statistically significant effect of dairy product consumption on weight loss and only when paired with a strict caloric restriction. His one abstract on the use of dairy products without caloric restriction showed no weight loss, but did report a differential loss of body fat. Two of his three reports using a strict caloric restriction along with the consumption of dairy products described weight loss and all three reported fat loss in the dairy groups. However, his reports are methodologically flawed, have not been replicated by others, have reported results that diverge from the rest of the body of relevant research, and exist only as two abstracts and two reports with incomplete data. In studies not carried out by that author, the body of research clearly shows that neither calcium-supplementation nor increased dairy product supplementation promote statistically significant weight loss or loss of body fat, either in the presence or absence of caloric restriction.

Prospective observational studies have not shown dairy products or calcium supplements to be associated with loss of body weight or body fat. In some subgroups of some studies, dairy or calcium use has been associated with slowed rate of gain of weight or body fat over time or with lower weight or body fat at a single time point. Such associations, however, may relate to other dietary and lifestyle factors, and cannot be causally attributed to dairy products or calcium.

6. Dairy Industry Promotional Literature Is Deceptive

Dairy advertisers rely on 35 studies⁸⁵ to support their claims, which are set forth on the Web site <http://www.nationaldairycouncil.org/nationaldairycouncil/healthyweight/science>. These studies are either relied upon or, in some cases, cited in the challenged television and print advertisements. An examination of these studies reveals that dairy advertisers have distorted the results and significance of the studies both in their characterization and presentation of the data

⁸⁵ See National Dairy Council's "Dairy's Role in Weight Management" Fact Sheet, attached as Exhibit 23, accessed on April 8, 2005.

and have omitted relevant studies that refute their claim. Such distortions and omissions give a false and misleading impression to the reasonable consumer about the scientific validity of the claim that the daily consumption of three servings of dairy products will result in weight and fat loss.

- *Dairy advertisers include studies irrelevant to the dairy/weight loss hypothesis.* Of the 35 studies cited by dairy advertisers, three (**Layman (2003)**⁸⁶, **Pereira (2002)**⁸⁷, **Albertson (2003)**⁸⁸) did not even study or report on whether dairy products have any relationship with weight or body fat. Such inclusion in the supporting science exaggerates and distorts the truth to the reasonable consumer, and is deceptive.
- *Dairy advertisers heavily rely on observational studies that fail to show any causal relationship.* Of the 35 studies, 18 are observational and do not indicate any causal relationship between dairy and weight or fat loss.⁸⁹ Of these 18 observational studies,

⁸⁶ Layman D, et al. *A reduced ratio of dietary carbohydrate to protein improves body composition and blood lipid profiles during weight loss in adult women.* J Nutr. 2003; 133: 411-417.

⁸⁷ Pereira MA, Jacobs DR, Van Horn L, Slattery ML, Kartashov AI, Ludwig DS. *Dairy consumption, obesity, and the insulin resistance syndrome in young adults.* JAMA. 2002;287:2081-2089.

⁸⁸ Albertson AM, et al. *Ready-to-eat cereal consumption: its relationship with BMI and nutrient intake of children aged 4 to 12 years.* J Am Diet Assoc. 2003;103:1613-9.

⁸⁹ Jacqmain (2003); Lin (2000); Loos (2003); Novotny (2004); Phillips (2003); Skinner (2003); Barba (2005); Dicker D, Belnic Y, Goldsmith F, Green M, Nitzan-Kaluski D. *On the relationship between dietary calcium intake, body mass index and waist size.* Presented at the 13th European Congress on Obesity. International Journal of Obesity and Related Metabolic Disorders. 2004; Supplement 1(28):S59. Abstract; Newby PK, Muller D, Hallfrisch J, Qiao N, Andres R, Tucker KL. *Dietary patterns and changes in body mass index and waist circumference in adults.* Am J Clin Nutr. 2003;77:1417-1425; Newby PK, Muller D, Hallfrisch J, Andres R, Tucker KL. *Food patterns measured by factor analysis and anthropometric changes in adults.* Am J Clin Nutr 2004;80:504-513; Drapeau V, Despres JP, Bouchard C, et al. *Modifications in food-group consumption are related to long-term body-weight changes.* Am J Clin Nutr. 2004; 80:29-37; Moore LL, et al. *Dietary predictors of excess body fat acquisition during childhood.* Circulation 2004;109:5, No. 3; Moore LL, Singer M, Bradlee ML, Gao D, Hood M, Ellison RC. *Low intakes of dairy product in early childhood may increase body fat acquisition.* Obes Res. 2003;11:130-OR; Kabrnova K, Braunerova R, Aldhoon B, Hlavaty P, Wagenknecht M, Kunesova M, Parizkova J, Hainer B. *Association of changes in macronutrient and calcium intakes with body weight change in obese subjects.* Presented at the 13th European Congress on Obesity. International Journal of Obesity and Related Metabolic Disorders. 2004; Supplement 1(28):S138. Abstract; Lelovics Z, Tarnavolgyi, G. *Relation between calcium intake and obesity.* Presented at the 13th European Congress on Obesity. International Journal of Obesity and Related Metabolic Disorders. 2004; Supplement 1(28):S169. Abstract; Mirmiran P, Esmailzadeh A, Azizi F. *Dairy consumption and body mass index: An inverse relationship.* International Journal of Obesity. 2005; 29:115-121; Ochner CN, Lowe MR. *Opposing effects of calcium and caloric intake on weight regain after diet.* Presented at the 13th European Congress

seven have only been published in abstract form, and three are studies of overall food patterns where dairy consumption is grouped with other eating behaviors that do not directly address the question of whether dairy, calcium, or milk consumption influences body weight or fatness. Moreover, dairy advertisers misrepresent the results of the observational studies on which they rely. In particular, none of the observational studies reported weight loss over time. Such heavy reliance on studies that fail to show any causal relationship distorts the truth to the reasonable consumer and is deceptive.

- *Dairy advertisers rely on a large number of review articles that merely summarize studies otherwise cited by dairy advertisers.* Of the 35 studies, seven are review articles that merely review studies that are already cited by dairy advertisers.⁹⁰ Review papers summarize an existing body of literature, but do not add any new data to the body of literature. In fact, the FDA does not consider review articles to be part of the body of evidence.⁹¹ Identifying review articles as supporting science exaggerates and distorts the truth to the reasonable consumer (who does not know the difference between a review article and a randomized controlled therapeutic trial), and is deceptive.
- *Dairy advertisers omit relevant studies that do not support their position.* Dairy advertisers fail to include 19 relevant studies on dairy and weight loss that do not support their hypothesis.⁹²

on Obesity. *International Journal of Obesity and Related Metabolic Disorders*. 2004; Supplement 1(28):S143. Abstract; Tsakalou Z, Yannakoulia M, Fotios A, Terzidou M, Kokkevi A, Sidossis L. *Prevalence of obesity/overweight and eating habits in Greek adolescents*. Presented at the 13th European Congress on Obesity. *International Journal of Obesity and Related Metabolic Disorders*. 2004; Supplement 1(28):S203. Abstract.

⁹⁰ Zemel MB. *Role of dietary calcium and dairy products in modulating adiposity*. *Lipids*. 2003;38:139-146; Parikh SJ, et al. *Calcium intake and adiposity*. *Am J Clin Nutr*. 2003; 77:281-287; Teegarden D, et al. *Symposium: Dairy product components and weight regulation*. *J Nutr*. 2003; 133: 243S-256S; Heaney RP, et al. *Normalizing calcium intake: Projected population effects for body weight*. *J Nutr*. 2003; 133:268S-270S; Davies KM, et al. *Calcium intake and body weight*. *J Clin Endocrinol Metab*. 2000; 85(12): 4635-4638; Zemel MB, et al. *Regulation of adiposity by dietary calcium*. *FASEB J*. 2000; 14:1132-1138; St-Onge MP, et al. *Dietary fats, teas, dairy, and nuts: potential functional foods for weight control*. *AJCN* 2005;81:7-15.

⁹¹ See FDA's Interim Evidence-based Ranking System for Scientific Data.

⁹² Harvey-Berino (2004); Jensen (2001); Bowen (2004); Wosje (2004); Barr (2003); Lau EMC, Woo J, Lam V, Hong A. *Milk supplementation of the diet by postmenopausal Chinese women on a low calcium intake retards bone loss*. *J Bone Miner Res*. 2001;16:1704-1709; Barr SI, McCarron DA, Heaney RP, et al. *Effects of increased consumption of fluid milk on energy, nutrient intake, body weight, and cardiovascular disease risk factors in healthy older adults*. *J Am Diet Assoc*. 2000;100:810-817; Chan GM, Hoffman K, McMurry M. *Effects of dairy products on bone and body composition in pubertal girls*. *J Pediatr*. 1995;126:551-556; Cadogan J, Eastell R, Jones N, Barker ME. *Milk intake and bone mineral acquisition in adolescent girls: randomised, controlled intervention trial*. *BMJ*. 1997;315:1255-1260; Merrilees MJ, Smart EJ, Gilchrist NL, et al. *Effects of dairy food supplements on bone mineral density in teenage girls*. *Eur J Nutr*. 2000;39:256-262; Prince RL, Devine A, Dick I, et al. *The effects of calcium*

- *Dairy advertisers' entire campaign is based solely on only two randomized controlled trials, both of which are of poor quality, insufficient relevance, refuted by the body of scientific evidence, and authored by a researcher with serious conflicts of interest.*

C. Dairy Advertisers Fail to Disclose the Health Problems Associated with Dairy Products

Overall, milk and other dairy products are not necessary in the diet—there is plenty of calcium in green leafy vegetables, fortified juices, and other foods with health advantages milk lacks. More importantly for this petition, dairy products, whether non-fat, reduced-fat, or full-fat, present other dangers, which dairy advertisers fail to disclose.

1. Osteoporosis

Milk is touted for preventing osteoporosis, yet clinical research shows otherwise. The Nurses' Health Study,⁹³ which followed more than 75,000 women for 18 years, showed no protective effect of increased milk consumption on fracture risk. An Australian study⁹⁴ showed similar results. Additionally, other studies have found no protective effect of dairy calcium on bone.⁹⁵

supplementation (milk powder or tablets) and exercise on bone density in postmenopausal women. J Bone Miner Res. 1995;10:1068–1075; Devine A, Prince RL, Bell R. Nutritional effect of calcium supplementation by skim milk powder or calcium tablets on total nutrient intake in postmenopausal women. Am J Clin Nutr. 1996;64:731–737; Storm D, Eslin R, Porter ES, et al. Calcium supplementation prevents seasonal bone loss and changes in biochemical markers of bone turnover in elderly New England women: a randomized placebo-controlled trial. J Clin Endocrinol Metab. 1998;83:3817–3825; Cleghorn DB, O'Loughlin PD, Schroeder BJ, Nordin BEC. An open, crossover trial of calcium-fortified milk in prevention of early postmenopausal bone loss. Med J Aust. 2001;175:242–245; Dibba B, Prentice A, Ceesay M, Stirling DM, Cole TJ, Poskitt EME. Effect of calcium supplementation on bone mineral accretion in Gambian children accustomed to a low-calcium diet. Am J Clin Nutr. 2000;71:544–549; Lloyd T, Andon MB, Rollings N, et al. Calcium supplementation and bone mineral density in adolescent girls. J Am Med Assoc. 1993;270:841–844; Riggs BL, O'Fallon WM, Muhs J, O'Connor MK, Kumar R, Melton LJ III. Long-term effects of calcium upplementation on serum parathyroid level, bone turnover, and bone loss in elderly women. J Bone Miner Res. 1998;13:168–174; Ricci TA, Chowdhury HA, Heymsfield SB, Stahl T, Pierson RN Jr, Shapses SA. Calcium supplementation suppresses bone turnover during weight reduction in postmenopausal women. J Bone Miner Res. 1998;13:1045–1050; Dawson-Hughes B, Harris S, Krall EA, Dallal GE. Effect of calcium and vitamin D supplementation on bone density in men and women 65 years of age or older. N Engl J Med. 1997;337:670–676.

⁹³ Feskanich D, Willet WC, Stampfer MJ, Colditz GA. *Milk, dietary calcium, and bone fractures in women: a 12-year prospective study. Am J Public Health. 1997;87:992-7.*

⁹⁴ Cumming RG, Klineberg RJ. *Case-control study of risk factors for hip fractures in the elderly. Am J Epidemiol. 1994;139:493-505.*

⁹⁵ Huang Z, Himes JH, McGovern PG. *Nutrition and subsequent hip fracture risk among a national cohort of white women. Am J Epidemiol. 1996;144:124-34; Cummings SR, Nevitt MC,*

Rather, bone integrity depends on reducing sodium and animal protein intake in the diet,⁹⁶ increasing intake of fruits and vegetables,⁹⁷ and exercising.⁹⁸ To the extent calcium is needed, adequate calcium is available from plant foods such as leafy green vegetables and beans, as well as calcium-fortified products such as breakfast cereals and juices.

2. Cardiovascular Disease

Dairy products—including cheese, ice cream, milk, butter, and yogurt—contribute significant amounts of cholesterol and fat to the diet.⁹⁹ Diets high in fat and saturated fat can increase the risk of several chronic diseases including cardiovascular disease. Non-fat dairy products are available, however, they pose other health risks as noted herein.

3. Cancer

Several cancers, particularly prostate cancer, are associated with dairy product consumption. In Harvard's Physicians Health Study¹⁰⁰ and Health Professionals Follow-up Study,¹⁰¹ higher daily consumption of milk was associated with increased risk of prostate cancer. One proposed explanation is that a large calcium intake reduces vitamin D activation within the body. Vitamin D protects the prostate gland from cancerous changes. Milk consumption also increases the concentration of insulin-like growth factor (IGF-I) in the bloodstream.¹⁰² In one study, men with

Browner WS, et al. *Risk factors for hip fracture in white women*. N Engl J Med. 1995;332:767-73.

⁹⁶ Finn SC. *The skeleton crew: is calcium enough?* J Women's Health 1998;7(1):31-6; Nordin CBE. *Calcium and osteoporosis*. Nutrition. 1997;3(7/8):664-86; Reid DM, New SA. *Nutritional influences on bone mass*. Proceed Nutr Soc. 1997;56:977-87.

⁹⁷ Tucker KL, Hannan MR, Chen H, Cupples LA, Wilson PWF, Kiel DP. *Potassium, magnesium, and fruit and vegetable intakes are associated with greater bone mineral density in elderly men and women*. Am J Clin Nutr. 1999;69:727-36.

⁹⁸ Prince R, Devine A, Dick I, et al. *The effects of calcium supplementation (milk powder or tablets) and exercise on bone mineral density in postmenopausal women*. J Bone Miner Res. 1995;10:1068-75.

⁹⁹ Pennington JAT. *Bowes and Churches Food Values of Portions Commonly Used*, 17th ed. New York: Lippincott, 1998.

¹⁰⁰ Chan J, Stampfer M, Ma J, et al. *Dairy products, calcium, and prostate cancer risk in the Physicians' Health Study*. Am J Clin Nutr. 2001 Oct;74(4):549-54.

¹⁰¹ Giovannucci E, Rimm EB, Wolk A, Ascherio A, Stampfer MJ, Colditz GA, Willett WC. *Calcium and fructose intake in relation to risk of prostate cancer*. Cancer Res. 1998a;58:442-7.

¹⁰² Outwater JL, Nicholson A, Barnard N. *Dairy products and breast cancer: the IGF-I, estrogen, and bGH hypothesis*. Medical Hypothesis. 1997;48:453-61; Chan JM, Stampfer MJ, Giovannucci E, et al. *Plasma insulin-like growth factor-1 and prostate cancer risk: a prospective study*. Science. 1998;279:563-5; World Cancer Research Fund. *Food, Nutrition, and the Prevention of Cancer: A Global Perspective*. Am Inst Cancer Research. Washington, D.C.: 1997.

the highest levels of IGF-I had more than four times the risk of prostate cancer compared with those who had the lowest levels.¹⁰³

Ovarian cancer has also been linked to the consumption of dairy products.¹⁰⁴ The presumed mechanism relates to the milk sugar lactose, which is broken down in the body into another sugar, galactose. In turn, galactose is broken down further by enzymes. When dairy product consumption exceeds the enzymes' capacity to break down galactose, it can build up in the blood and may affect a woman's ovaries. Some women have particularly low levels of these enzymes, and when they consume dairy products on a regular basis, their risk of ovarian cancer can be triple that of other women.

4. Lactose Intolerance

Lactose intolerance is common among many populations, affecting approximately 95 percent of Asian Americans, 74 percent of Native Americans, 70 percent of African Americans, 53 percent of Mexican Americans, and 15 percent of Caucasians.¹⁰⁵ Symptoms, which include gastrointestinal distress, diarrhea, and flatulence, occur because these individuals do not have the enzymes that digest the milk sugar lactose.

5. Health Concerns of Children

Milk proteins, milk sugar, fat, and saturated fat in dairy products may pose health risks for children and lead to the development of chronic diseases such as obesity, diabetes, and formation of atherosclerotic plaques that can lead to heart disease.

Cow's milk products are very low in iron. If they become a major part of a child's diet, iron deficiency is more likely.¹⁰⁶ Additionally, food allergies are common results of milk consumption, particularly in children.¹⁰⁷ A recent study also linked cow's milk consumption to chronic constipation in children.¹⁰⁸ Researchers suggest that milk consumption resulted in perianal sores and severe pain on defecation, leading to constipation.

¹⁰³ Chan (1998).

¹⁰⁴ Larsson SC, Bergkvist L, Wolk A. *Milk and lactose intakes and ovarian cancer risk in the Swedish Mammography Cohort*. Am J Clin Nutr. 2004; 80;5:1353-57; Fairfield KM, Hunter DJ, Colditz GA, Fuchs CS, Cramer DW, Speizer FE, Willett WC, and Hankinson SE; *A prospective study of dietary lactose and ovarian cancer*. Int J Cancer. 2004;110: 271-77; Cramer DW, Harlow BL, Willett WC. *Galactose consumption and metabolism in relation to the risk of ovarian cancer*. Lancet. 1989;2:66-71.

¹⁰⁵ Bertron P, Barnard ND, Mills M. *Racial bias in federal nutrition policy, part I: the public health implications of variations in lactase persistence*. J Natl Med Assoc. 1999;91:151-7.

¹⁰⁶ Faldella G, Corvaglia L, Lanari M, Salvioli GP. *Iron balance and iron nutrition in infancy*. Acta Pediatr Suppl. 2003;91:82-5

¹⁰⁷ Moneret-Vautrin DA. *Cow's milk allergy*. Allerg Immunol (Paris). 1999;31:201-10

¹⁰⁸ Iacono G, Cavataio F, Montalto G, et al. *Intolerance of cow's milk and chronic constipation in children*. N Engl J Med. 1998; 339:110-4.

IV. CONCLUSION

The advertisements linking the consumption of dairy products to weight or fat loss constitute deceptive advertising under federal law. In the instant case, the advertisements make the express and implied claims that consuming at least 24 ounces of dairy products every day will result in greater weight and fat loss than just cutting calories alone, and that it is the special mix of nutrients in dairy that makes this happen. In other words, the advertisements convey to the reasonable consumer that simply adding dairy products to one's diet will cause weight and body fat loss. Moreover, the omission of material information gives a false and misleading impression to the reasonable consumer about the scientific support for these claims.

A. These Advertisements Are False and Misleading

As noted above, the Commission will find an advertisement deceptive if it contains a representation or omission that is likely to mislead consumers. In the instant case, these claims are just not true—there is no acceptable scientific basis that lends any credence to them. The diet actually being promoted by dairy advertisers is if you want to lose weight, you have to reduce your daily calorie intake by 500 calories. In fact, that is the diet. Reduce your calorie intake by 500 calories. Dairy advertisers have, however, disguised the actual diet technique with false claims about the effect that dairy products play in losing weight and body fat. As such, the claims made in the dairy weight loss promotion are false and misleading.

The advertisements are further misleading because they are ambiguous as to whether a calorie-restricted diet is part of the weight loss effect and as to the severity of the calorie restriction. A reasonable consumer would have the impression that, perhaps, they just need to “watch their calories,” when in reality, they would have to drastically decrease their caloric intake to see any effect. Zemel's studies—the only studies that purport to show a cause and effect relationship—cut calories by 500 per day, which is about $\frac{1}{4}$ of the total calorie intake of the average person. It is extremely unlikely that many consumers would be willing to replicate the conditions of his study (24 oz milk/day, 500 cal/day restriction for six months), which may be why dairy advertisers fail to plainly disclose this information.

These misrepresentations are further compounded by dairy advertisers' omission of material information regarding the large body of science that contradicts their hypothesis. Because the consumer assumes from the representations a set of facts opposite to that which actually exists, disclosure of the full body of relevant science is necessary to prevent the claims from being misleading.

Finally, the weight-loss promotion advertisements that fail to limit the supposed effect to the consumption of lowfat or fat-free dairy products are in direct violation of FDA prohibitions on making a health claim for foods that contain more than 4 grams of saturated fat or 60 milligrams of cholesterol per serving.¹⁰⁹ The FTC scrutinizes any health claim made for a food that contains more than the pre-determined levels of these nutrients to ensure the claim is truthful and

¹⁰⁹ 21 C.F.R. § 101.14(a)(4).

adequately qualified. To prevent deception, the health claim should include a disclosure that conveys the presence and significance of the risk-increasing nutrient, which these advertisements do not.

B. Reasonable Consumer

The next step in identifying deception in an advertisement requires the Commission to consider the representation from the perspective of a consumer acting reasonably, or as an average consumer would, under the circumstances. Commission precedent establishes that an advertisement that can reasonably be interpreted in a misleading way is deceptive, even though other, non-misleading interpretations may be equally possible. Furthermore, an interpretation will be presumed reasonable and material if it is the claim the advertiser attempted to convey.

The FTC Deception Policy states:

Depending on the circumstances, accurate information in the text may not remedy a false headline because reasonable consumers may glance only at the headline. Written disclosures or fine print may be insufficient to correct a misleading representation. Other practices of the company may direct consumers' attention away from the qualifying disclosures. Oral statements, label disclosures, or point-of-sale material will not necessarily correct a deceptive representation or omission. Thus when the first contact between a seller and a buyer occurs through a deceptive practice, the law may be violated even if the truth is subsequently made known to the purchaser. Pro forma statements or disclaimers may not cure otherwise deceptive messages or practices. (internal citations omitted.)

Furthermore, “[a]dvertisers cannot say ‘X,’ qualifying it with a disclaimer that says ‘not X,’ and expect consumers to make much sense of it. Under FTC law, the advertiser bears the burden of ensuring that the qualification is adequate in placement, prominence and content. The risk of miscommunication is on the advertiser, not on the government and, most importantly, not on the public.”¹¹⁰

In the instant case, there is ample evidence that the average consumer would interpret the advertisements to mean that consuming at least 24 ounces of dairy products every day will result in weight and fat loss and any qualifications or cautions made in the advertisements do not cure the deception.

¹¹⁰ Remarks of J. Howard Beales, January 14, 2004, available at <http://www.ftc.gov/speeches/beales/040114foodanddruglawinstitute.pdf>.

C. Materiality

Finally, a representation must be material, that is, likely to affect a consumer's choice or use of a product or service. Material misrepresentations are likely to cause injury to the consumer, in that they would have chosen differently but for the deception. Express claims, implied claims which the advertiser intended, and health claims are presumptively material.¹¹¹

Additionally, omissions, "where the seller knew, or should have known, that an ordinary consumer would need omitted information to evaluate the product or service, or that the claim was false, materiality will be presumed because the manufacturer intended the information or omission to have an effect."¹¹²

The advertisements at hand are presumptively material because they make health claims on which dairy advertisers intend for consumers to base their purchasing decision.

* * *

Literally hundreds of millions of Americans are exposed to these advertisements on a daily basis. While the advertisements have been effective at conveying their message, the message is unequivocally deceptive, misleading, and dangerous. Given the tremendous public saturation of the weight loss promotion, putting a stop to any further dissemination of the fraudulent, false, and misleading information regarding the purported weight and fat loss benefits of dairy products is urgently needed. The continued promotion of a grossly oversimplified and false characterization of dairy's relationship to obesity only serves to aggravate the tremendous toll of the disease. Dairy advertisers should be stopped and held accountable for making health claims that encourage individuals to consume a product that offers none of the alleged benefit, but causes other harmful consequences.

¹¹¹ FTC Deception Policy.

¹¹² *Id.*