CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST
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Food and Drug Administration
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Rockville, MD 20852

Re: FDA Task Force on Consumer Health Information for Better Nutrition (Docket No. 03N-0069)

The Center for Science in the Public Interest (CSPI) is filing these comments in response to the request for stakeholder viewpoints by the Task Force on Consumer Health Information for Better Nutrition.

Introduction

CSPI believes that the Health Claims Initiative should be withdrawn because (1) the First Amendment of the U.S. Constitution does not require the use of "qualified" claims if the Congressionally mandated standard of "significant scientific agreement" (SSA) cannot be satisfied; (2) the use of such claims based upon an exercise of the Food and Drug Administration's (FDA) "enforcement discretion" is contrary to the Nutrition Labeling and Education Act's (NLEA) requirement that health claims for foods be issued pursuant to a notice and comment rulemaking proceeding or authoritative statement; (3) the FDA violates the Administrative Procedure Act (APA) by its decision to forego enforcement actions mandated by the Federal Food, Drug and Cosmetic Act against companies making "qualified claims;" and (4) the Initiative undermines the First Amendment rights that it attempts to protect. Despite CSPI's misgivings about the Agency's response to recent court decisions addressing First Amendment

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protections for commercial speech, we will, nonetheless, respond to the specific questions set forth by the Agency in its request for comments.

1. What body of scientific evidence do you think should be adequate for a qualified health claim?

We agree with the FDA's conclusion that if qualified claims are permitted for foods, they should be based on the weight of the scientific evidence as set forth in the December 2002 *Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements*.[1] If claims are to be meaningful to consumers, they must be consistent with the available scientific evidence. Health claims will cease to have meaning if the FDA frequently approves qualified claims and just as frequently withdraws them in light of new scientific evidence.

We believe that the FDA should heed the warnings of the National Academy of Sciences' Institute of Medicine and be cautious in authorizing qualified claims. The IOM explained that:

> Claims about nutrient-disease relationships are more easily made than scientifically supported. Because the implications for public health are so important, caution is urged prior to accepting such claims without supportive evidence from appropriately designed, typically large clinical trials.[2]

The IOM stated that further study of an "appealing hypothesis" may result in a finding that the nutrient actually causes harm. For example, although preliminary evidence suggested that beta-carotene could reduce the risk of lung cancer, clinical intervention trials later demonstrated that beta-carotene supplements actually increased the risk of lung cancer in smokers."[3] The IOM

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[1] Available at http://www.cfsan.fda.gov/dms/guidance.html [hereinafter *Guidance*].

[2] National Academy of Sciences, Institute of Medicine, Evolution of Evidence for Selected Nutrient and Disease Relationships 58 (2002).

[3] *Id.* at 6.

study indicates that health claims should be based on a strong evidentiary standard as originally envisioned by Congress in the NLEA.

Moreover, a newly released market analysis entitled *FDA Approved Health Claims in Food* concludes that one important factor influencing the purchase of products containing health claims is the degree to which consumers are skeptical of the claims because of past experience with nutrition advice that has been reversed, e.g., eat margarine/not butter followed by eat butter/not margarine. The report concludes that "codification of specific health claims through the FDA may result in a less suspicious public, one that is willing to eat more healthfully under the guidance of the government."[4] The report explained that "[a]n FDA approval should . . . carry more credibility due to the rigorous guidelines outlined for each claim."[5] The FDA's decision to permit qualified claims is inconsistent with the results of this study because it sanctions claims that are likely to be the subject of future controversy within the scientific community. Thus, the new FDA policy may result in raising public suspicions about dietary advice and threaten the effectiveness of all health claims, including those based on significant scientific agreement.

2. What types of safety concerns should be factored into the FDA's decision-making?

Whenever a claim is being considered – whether it be a claim meeting the significant scientific agreement standard or a qualified claim, the FDA should consider the impact of the claim on the public's health. Among the questions that the agency should ask is whether the claim would encourage people to consume:

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[4] Mintel, *FDA Approved Health Claims in Food* 67 (Apr. 2003) *at* www.mintel.com.

[5] *Id.* at 12.

- A nutrient at levels that exceed the Upper Tolerable Intake Levels (UL) set by the National Academy of Sciences (NAS) or a supplement at levels that are unsafe;

For example, vitamin A (retinol) can be toxic at high doses, and it weakens bones at doses close to the RDA.[6] The FDA must, therefore, deny a claim or include a warning about over consumption if it is likely that a claim could trigger consumption beyond a safe upper limit.

- A nutrient that puts some population groups at risk;

The FDA must also consider the effect that a claim would have on particular population groups such as the elderly, young children, pregnant women, or others. For example, a claim that promotes the consumption of vitamin A (as retinol) could raise the risk of birth defects. Similarly, a claim for high doses of beta-carotene could raise the risk of cancer in smokers.

- A nutrient that often occurs in the same foods as a detrimental substance;

A claim for a nutrient in tuna and swordfish might lead people to consume more mercury. Similarly, a claim for the omega-3 fats in eggs could lead people to consume excess cholesterol, and a claim for the unsaturated fats in oils or nuts could lead people to consume excess calories. If the FDA were to approve a claim for one of those nutrients, it should require a warning to alert consumers to the potential harm caused by consuming the detrimental substance.

- A nutrient that might deter people from seeking medical evaluation or treatment;

Approval of qualified health claims should also take into account the likelihood that consumers will use a supplement or a food containing a particular nutrient instead of seeking prompt medical evaluation or treatment. For example, a claim that vitamin E or B-vitamins (folic acid, vitamin B-6, vitamin B-12) can reduce the risk of heart disease might keep people

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[6] Vitamin A intake and hip fractures among postmenopausal women. JAMA. 2002 Jan 2; 287(1):47-54.

from taking medications that could lower their risk. A claim that saw palmetto can treat benign prostatic hypertrophy could keep people from seeking a medical evaluation for prostate cancer. It is essential that the FDA determine whether consumers will understand warnings to seek medical help before attempting to treat or prevent disease on their own.

3. What specific claims do you think are currently ready under the new guidance?

We do not believe that any claims should be considered until the FDA conducts consumer research necessary to answer questions 4 and 5 below.

4. On what issues are disclaimers valuable, or not valuable, in preventing consumers from being misled, and do you have data to support your view?

Disclaimers are not helpful in informing consumers about the uncertainty of the science unless they are very detailed. As the Federal Trade Commission (FTC) staff found in its *Generic Copy Test of Food Health Claims in Advertising*,[7] only strong disclaimers including explicit references to inconsistent study results or ongoing scientific debate "can have a significant impact on consumer perceptions of the level of proof underlying a health claim."[8] But "more mildly qualified claims . . . did not lower mean certainty ratings significantly." The report further noted that "it is important to recognize . . . that subtle changes in the wording or placement of claims and qualifying disclosures could have a significant impact on how consumers interpret an advertisement."[9]

Moreover, in an era of information overload, consumers may not read the disclaimer or

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[7] Dennis Murphy, Theodore H. Hoppock et. al, *Generic Copy Test of Food Health Claims in Advertising, A Joint Staff Report of the Bureaus of Economics and Consumer Protection,* FTC (Nov. 1998).

[8] *Id.* at E-8.

[9] Press Release, "FTC Releases the Food Copy Test Results" (Nov. 18, 1998).

may simply skim it without understanding its significance. For example, the Dietary Supplement Health and Education Act (DSHEA) requires that the label of any dietary supplement product that contains a "structure/function" claim include the following disclaimer: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."[10]

One study involving the DSHEA-mandated disclaimer found that consumers do not interpret this disclaimer as so-called common sense would dictate. This study found that consumers evaluated the claim in diverse ways: several participants in the study were unaware of the lack of substantiation for the claims because they had either never read the disclaimer or had simply misread it to say that the FDA had in fact evaluated the claim.[11]

A survey commissioned by AARP on dietary supplement use and knowledge among older consumers confirms that the DSHEA disclaimer may not function as intended. Most of the respondents in the study indicated that they had either never seen the disclaimer or did not know if they had ever seen it (59 percent).[12]

Numerous other disclosures and disclaimers are mandated for various consumer products, and the FDA should thoroughly review all of the existing research on their effectiveness as part of this proceeding. CSPI believes that disclaimers and qualifying statements must be tested on

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[10] FDCA § 403(r)(6)C), 21 U.S.C § 343(r)(6)(C).

[11] Marlys J. Mason and Debra L. Scammon, *Product and Brand Decisions in a Complex Information Environment: The Case of Supplements*, working paper, Department of Marketing, University of Utah, *discussed in* Merles J. Mason and Debra L. Scammon, *Health Claims and Disclaimers: Extended Boundaries and Research Opportunities in Consumer Interpretation*, 19 Journal of Public Policy & Marketing 6 (LEXIS version) (Spring 2000).

[12] AARP Public Policy Institute, *Dietary Supplements and Older Consumers Data* Digest 66 (Dec. 2001).

consumers before determining, which, if any, should be included on product labels or in advertising. The court in the *Pearson* case acknowledges that empirical evidence has a role to play in determining the effectiveness of disclaimers and disclosures.[13]

In the past, disclaimers or qualifiers have informed consumers that they need to purchase additional items in order to use the product being purchased. For example, the phrases "batteries not included," "assembly required," or "add chicken or beef" commonly appear on labels of consumer products. In addition, many food product labels that depict the food being served as a meal carry the words "serving suggestion" so that consumers are aware that the actual product does not contain all of the ingredients pictured.

Disclaimers are also useful in situations where consumers want to know ingredient origins. For example, "not from concentrate" makes it clear to consumers that they are not buying a product that has been frozen and reconstituted. Similarly, "not a non-caloric product" alerts consumers to the fact that although a product may contain an artificial sweetener, it still has calories. It is also helpful for consumers to know that certain artificial sweeteners may have a laxative effect.

But information indicating that the FDA has not reviewed a claim does not help consumers at all. It does not provide them with due certainty that claims inducing them to buy a product are justified. Nor does the fact that the claim states that it is based on preliminary evidence offer the consumer helpful advice. The consumer cannot evaluate the various studies that have been done to reach a rational conclusion as to whether it is worth buying the product.

This is far different from the disclaimers that let consumers know that the product will

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[13] Pearson, 164 F.3d at 659-60 (the court "does not rule out" the possibility that the government could demonstrate with empirical evidence that disclaimers would bewilder consumers and fail to correct for deceptiveness).

not work without batteries or until it is assembled or that a meal will be incomplete unless the consumer adds meat to a meal starter depicted as having meat. At the point of purchase, the consumer can determine if it is worth buying the batteries, getting a product that requires assembly, or getting a meal starter that requires the addition of other ingredients before dinner can be served. It is a far cry from a disclaimer that basically tells consumers "caveat emptor" – the FDA has abdicated its responsibility to ensure the reliability of a health claim.

5. What kinds of empirical data should the FDA rely upon to show that consumers are, or are not, misled by claims?

Focus groups are a useful first step to determine if further research is needed The focus groups that have been conducted so far show that disclaimers do not function effectively.[14] Thus, such studies need to be supplemented with telephone surveys and mall intercept studies. As part of these studies, the FDA needs to obtain definitive data on consumer expectations with respect to health claims. For example, it must determine: (1) whether consumers pay attention to health claims; (2) to what extent the presence of a health claim influences the purchasing decision; (3) whether consumers believe that claims are approved by the FDA; (3) whether their buying decision depends on the perception that a claim has government approval; (4) whether consumers would be less likely to buy a product that had a preliminary health claim than one meeting the SSA standard; and (5) whether they will read and comprehend disclaimers.

The FDA also should research whether distinguishing between structure/function claims and health claims for regulatory purposes is helpful to consumers. It is no secret that prior to the implementation of the Health Claims Initiative, manufacturers whose claims could not meet the significant scientific agreement standard or contained disqualifying levels of particular nutrients

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[14] *See* discussion *infra* note 16 and accompanying text.

could present virtually the same claims reworded as structure/function claims.[15]

Moreover, in 1999, nine FDA focus groups found that consumers could not tell the difference between structure/function claims and health claims.[16] Nor are consumers aware of the legal and evidentiary distinctions between them. Consumer understanding of these distinctions has not improved in the four years since those focus groups were convened. This problem is discussed in the cover story of the June 2003 *Nutrition Action Healthletter* published by CSPI.[17]

6. Should conventional foods and dietary supplements be treated the same or treated differently, and why?

Each category should be treated differently. Although everyone has to eat, only 50-60% of consumers use supplements. Consumers who take supplements may be more health conscious

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[15] For example, Kellogg briefly test marketed a new line of functional foods called "Ensemble" that contain psyllium. The product line consisted of 22 items including breads, pastas, frozen entrees such as lasagna, snack chips, cakes and cookies. While all of the products contained either psyllium or oat bran, which have been recognized by the FDA as being useful in reducing cholesterol and lowering the risk of heart disease, some items contain too much fat or inadequate nutritional value to qualify for the FDA-approved claim. To overcome these restrictions, Kellogg made structure/function claims on products not qualifying for health claims. For example, the Ensemble Carrot Cake label states: "made with a natural soluble fiber that actively works to promote heart health." International Association of Consumer Food Organizations, *Functional Foods Public Health Boon or 21st Century Quackery?* 48-49 (1999) (June 2003).

[16] General Accounting Office, Food Safety, Improvements Needed in Overseeing the Safety of Dietary Supplements and "Functional Foods," 23 GAO/RCED-00-156 (July 2000).

[17] It has also become apparent that some manufacturers believe that structure/function claims – which are significantly shorter and more positive and require no FDA approval – result in better market results than health claims. Linda Gilbert, *Marketing Functional Foods: How to Reach Your Target Audience*, AgBioForum 272-290 (Winter 2000). A national study of public attitudes and actions toward shopping and eating found that those termed "food as medicine" shoppers (i.e. those who strongly believe foods can be used to reduce their use of drugs) look for "positive health claims," which correspond to what is commonly referred to as structure/function claims. They favored "supports the immune system" over "may reduce the risk of cancer" or "helps to maintain healthy cholesterol levels" over "may reduce risk of heart disease." *Id.*

than consumers who do not. Furthermore, dietary supplements are typically sold as pills or capsules. In contrast, food is sold whole or processed and is consumed for its taste as well as its nutritive value. Practically all foods are safe for children over two years of age to consume (other than those that present choking hazards). In contrast, only some dietary supplements are safe for children to consume. Thus, these two product categories present different health considerations and should be regulated accordingly.

7. The Federal Trade Commission's policy is not an appropriate model for qualified claims.

The FDA has felt compelled in this proceeding to emulate the policies of the FTC. However, other than one action last year, the FTC has not obtained a single cease and desist order against a food advertiser for making false and misleading health claims since it issued its Enforcement Policy Statement (EPS) on Food Advertising in 1994 – more than eight years ago! Moreover, the FTC has ignored numerous complaints about false and misleading health claims in food ads that have been brought to its attention by CSPI and others. We thus question the FTC's commitment to consumer protection in this area and are dismayed that the FDA would want to follow that agency's policies.

Moreover, the FTC staff's latest study of health claims, *Advertising Nutrition & Health Evidence from Food Advertising 1977-97*, is filled with shortcomings and methodological deficiencies, and should not be relied on to guide regulatory policy:

- The authors focus on the fact that more health claims were made prior to the NLEA than after its passage but neglect to discuss a fundamental issue – whether any of the pre-NLEA ads that they relied on were deceptive. Without question, many of them were. In 1989, the cover of *Business Week* magazine featured a story entitled "Can Corn Flakes Cure Cancer?" The subtitle read, "Of course not. But health claims for foods are becoming ridiculous. Here is what you should know."[18] Thus, the sample used by the

[18] *Business Week*, Oct. 9, 1989.

authors lacks legitimacy and taints the findings of their study.

- The FTC study is based solely on a review of print ads although the vast majority of food ads appear on television. Television ads are fundamentally different than print ads. TV advertisers have only 15-30 seconds to transmit a message to consumers while print advertisers utilize a medium that can contain numerous bits of information that cannot be easily fit into a broadcast ad. Thus, a review of print ads only does not accurately represent what is occurring in the food advertising marketplace.[19]

- The duration of the FTC study is problematic. The study ends in 1997, only four years after the FDA's health claims regulations were implemented. The study period for post-NLEA advertisements should have been longer in order to more fully assess the impact of the FDA's policies. In recent years, the use of FDA-approved health claims in advertising has become more prevalent as companies become more adept at using the FDA messages in marketing.[20]

The FDA's deference to and reliance on FTC policy is also improper because of the significant difference in each of the agencies' missions. This distinction was spelled out clearly by Congress in the legislative history of the NLEA, the statute itself, and by the FTC in its EPS issued in response to the FDA's implementation of the new law.

The House Committee on Energy and Commerce explained the specific purposes behind the NLEA:

> Health claims supported by . . . significant scientific agreement can reinforce the Surgeon General's recommendations and help Americans to maintain a balanced and healthful diet.[21]

A distinct section of the NLEA, section 2(c), entitled "Consumer Education," requires

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[19] The authors claimed that it was impractical to study food advertising on television because no archives existed to permit the development of a systematic sample. Pauline M. Ippolito and Janis K. Pappalardo, *Advertising Nutrition & Health Evidence from Food Advertising 1977-1997* E-2 (Sept. 2002). Yet, CSPI is aware of several commercial archiving companies that routinely provide such services

[20] *See* Mintel Report, *supra* note 4 at 69.

[21] House Committee on Energy and Commerce, Nutrition Labeling and Education Act of 1999, H.R. Doc. No. 538, 101st Cong., 2d Sess. 9-10 (1990).

the FDA to educate consumers about the availability of nutrition labeling and the importance of such information in maintaining healthy dietary practices.

The FTC discussed the FDA's educational mandate in its EPS setting forth guidance on the use of nutrient content and health claims in advertising:

> While the NLEA is designed in part to prevent deceptive and misleading claims on labels, Congress also intended that nutrient content and health claims *educate* consumers in order to assist them in maintaining healthy dietary practices. . . The NLEA also mandated that FDA undertake a consumer education effort to educate consumers about the new food label and the importance of diet to health. . . Therefore, in keeping with its recently expanded and unique jurisdictional mandate, the requirements set forth in FDA's regulations have a *broader* purpose than preventing false and misleading claims in food labeling.[22]

The FTC has also recognized the scientific expertise of the FDA and discussed its intention to give "great weight" to the FDA's scientific determinations in matters of nutrition and health.[23] It is, therefore, disturbing that given its broader mandate to educate and its greater scientific expertise, the FDA is essentially assuming the narrower mission of the FTC, deferring to its limited scientific expertise and limiting its goals to preventing false and misleading claims.

Simply informing the public that scientific evidence is preliminary does not educate consumers. Providing consumers with claims based on preliminary scientific evidence that may not bear the test of time is like giving consumers a coin to toss. Instead of taking a "buyer beware" approach, the FDA should be using its scientific expertise to educate consumers about truly valid claims that can be relied on to improve their health.

Lastly, the FDA's reliance on the FTC legal standard for consumer deception and court decisions enunciating that the FDA's only duty is to protect "a reasonable person" are

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[22] 59 Fed. Reg. 28388 (June 1, 1994). (Emphasis added).

[23] *Id.*

inappropriate since they do not represent current law involving misbranding. In its notice announcing the availability of the *Guidance*, the FDA states:

> The reasonable consumer standard more accurately reflects FDA's belief that consumers are active partners in their own health care who behave in health promoting ways when they are given accurate health information. In addition, the reasonable consumer standard is consistent with the governing first amendment law precluding the Government from regulating the content of promotional communication so that it contains only information that will be appropriate for a vulnerable or unusually credulous audience.[24]

The FDA is well aware that courts reviewing misbranding violations on product labels have – with rare exception – interpreted the FDCA as protecting "the ignorant, the unthinking, and the credulous consumer." In the *Guidance*, the FDA cites some of these cases but then concludes that the "reasonable consumer" approach is "the appropriate standard" based in part on a 1951 case, *U.S. v. 88 Cases, Birely's Orange Beverage*.[25] It ignores the fact that the most widely followed cases on this issue are far more recent than the *Birely* case.[26]

The FDA's reliance on Supreme Court language quoted in *Bolger v. Young Products Corporation* is also inappropriate because that case involved *advertising* not *labeling*. In *Bolger*, the Court held unconstitutional a state statute prohibiting the unsolicited mailing of advertisements for contraceptives. The FDA seized on language *Bolger* quoted from an earlier Supreme Court case holding unconstitutional a Michigan statute that banned reading materials inappropriate for children. In that earlier case, the Supreme Court said: "We have previously

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[24] 67 Fed. Reg. 78004 (Dec. 20, 2002).

[25] 187 F.2d 9967, 971 (3d Cir.), cert. den., 342 U.S. 861 (1951).

[26] U.S. v. Strauss, 999 F.2d 692 (2d Cir. 1993) "We have construed section 343 broadly, since the test is not the effect of the label on a reasonable consumer, but upon 'the ignorant, the unthinking and the credulous consumer'"; citing US. v. An Article . . . Sudden Change, 409 F.2d 734, 740 (2d Cir. 1969). and U.S. v. An article of Food . . . 'Manischewitz . . .Diet Thins,' 377 F. Supp. 746 (E.D.N.Y. 1974).

made clear that a restriction of this scope is more extensive than the Constitution permits, for the government may not "reduce the adult population . . . to reading only what is fit for children."[27]

The First Amendment cases discussed by the FDA ignore the fundamental distinctions between labeling and advertising. Food labeling is mandatory. Product labels are required to list ingredients, nutrition facts, net weight, a product identity statement, and the location of the manufacturer, packer or distributor. Print size and placement requirements are imposed. Because of these requirements, consumers have come to rely on labels to be accurate and dependable.

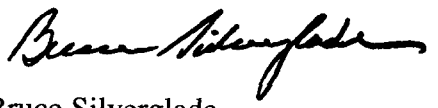
In contrast, there is no requirement that any attributes of food products be advertised. Superlative claims about the attributes of particular products are the norm and are often considered by regulatory officials to constitute "puffing." Thus, it is inappropriate for the FDA to base regulatory policies dealing with labeling on those developed for the purposes of regulating food advertising.

[27] 463 U.S. at 73 (citations omitted).

Conclusion

For the foregoing reasons, CSPI believes that the Health Claims Initiative should be withdrawn. In the event that this does not occur, the FDA needs to obtain appropriate consumer survey data to help the Agency determine the most effective way of protecting the public from misleading claims and educating consumers about diet and health. Qualified health claims for foods should not be authorized before such data is obtained.

Respectfully submitted,



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