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Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: Request for Comment on First Amendment Issues
Docket No. 02N-0209
67 Fed. Reg. 34942 (May 16, 2002)

The Center for Science in the Public Interest (CSPI) is filing these comments in response to the Food and Drug Administration's (FDA) *Federal Register* notice regarding the Agency's regulation of commercial speech. CSPI is a not-for-profit consumer education and advocacy organization based in Washington, D.C. CSPI was founded in 1971 and for the last three decades has been closely involved with matters pertaining to food labeling, safety, and nutrition. The following comments are limited to the impact of recent court decisions involving the commercial free speech doctrine on the FDA's regulation of foods and dietary supplements.

I. Introduction

CSPI is an ardent proponent of empowering consumers to make informed decisions about the products they purchase by providing them with well-supported, truthful and non-misleading information. That is why, for example, CSPI led the fight for mandatory nutrition information and Daily Values on practically all food labels in the U.S. The Nutrition Facts label provides consumers with information that they can use to promote their health.

Ironically, however, many segments of the food industry now cite the First Amendment's

commercial free speech doctrine as grounds for why the FDA should not move ahead with

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updating the Nutrition Facts label.¹ Such actions show that many companies, while claiming to favor free and open communication, in reality wish to rely on recent judicial decisions involving commercial speech to suit their own agenda.

We are concerned that the FDA is willing to give in to such specious arguments and rely on recent Supreme Court and Court of Appeal decisions involving the First Amendment doctrine of “commercial speech” as an excuse for failing to vigorously exercise its statutory authority in matters that serve the interest of consumers. Accordingly, CSPI questions the validity of this proceeding on both procedural and substantive grounds.

First, we believe that the FDA has approached this issue in an inappropriate procedural manner. Some of the court decisions the Agency is concerned with involve the constitutional validity of express statutory mandates assigned to the FDA by Congress. A public comment period is a less-than-ideal forum to discuss the implications of evolving constitutional law doctrine on the Agency’s statutory mandate. The appropriate forum for discussing the implications of recent court decisions on the Agency’s statutory mandate and its implementing regulations should, in the first instance, be Congress which enacted the legislation that led to the court decisions at issue here. It is not for the FDA, an executive branch Agency, to second guess the legislative branch and take the law into its own hands. Rather, it is Congress’s responsibility to sort through the implications of the judiciary’s pronouncements on the Agency’s statutory mandates and determine what, if any, changes are necessary in the Agency’s implementing regulation and policies.

¹ See, e.g. Comments of the Institute of Shortening and Edible Oils, Docket No. 94P-0036, Food Labeling: *Trans* Fatty Acids in Nutrition Labeling (64 Fed. Reg. 62746), Nov. 17, 1999, at 10-16.

The fact that FDA has chosen, nonetheless, to address this matter in an administrative proceeding, before Congress has acted, indicates that the Agency may be using recent court decisions as a pretext to fulfill a political agenda based on reducing regulation of the food and dietary supplement industries. Indeed, that course of action has strongly been urged by representatives of those industries in comments previously filed with the Agency.

Second, we believe the FDA has misrepresented the challenges that confront the Agency as a result of recent court decisions involving the commercial speech doctrine. The court decisions explicitly and implicitly referred to by the FDA in its *Federal Register* announcement² were typically brought by the regulated industries that were seeking to overturn consumer protection rules. Thus, if the FDA chooses to seek public comment, the Agency should be addressing how it can continue to fulfill the statutory mandate assigned to it by Congress notwithstanding court decisions that struck down portions of the Agency's statutory and/or regulatory framework. Instead, many of the FDA's requests for comment on specific issues, as set out in its *Federal Register* announcement, seem to be designed to ask how the Agency can expand the impact of the relevant court decisions at issue here to areas not expressly covered by the courts' determinations. The Agency's substantive approach again suggests that it is attempting to address a political issue — deregulation — under the guise of an analysis of constitutional law doctrine.

Five months ago, the Supreme Court reaffirmed in *Thompson v. Western States Medical Center* that the First Amendment does not protect commercial speech that either concerns

² The Agency explicitly mentioned *Thompson v. Western States Medical Center*, 535 U.S.____, 122 S. Ct. 1497 (Apr. 29, 2002). The appellate decision in *Pearson v. Shalala*, 164 F.3d 650 (D.C. 1999) is not explicitly referenced. But the Agency's questions on dietary supplements concerning the use of disclaimers or qualifications on claims go to the heart of that case.

unlawful activity or that is inherently misleading.³ Thus, the Supreme Court's most recent decision raises no barrier to the FDA's barring such speech.⁴ The more difficult problem, however, is determining when the Agency can impose restrictions on commercial speech that concerns a lawful activity and that is not inherently misleading.

Although the Supreme Court first articulated a test more than 20 years ago in *Central Hudson Gas & Elec. Corp. v. Public Service Commission of New York*,⁵ implementation of the test has resulted in split decisions in a number of cases.⁶ For example, in 2001, the Supreme Court held, in a 6-3 decision, that Massachusetts' restrictions on the location of outdoor and point-of-sale advertising of smokeless tobacco and cigars violate the First Amendment even though Massachusetts had an important interest in preventing the use of tobacco by minors.⁷ This year, the Supreme Court held, in *Western States*, a 5-4 decision,⁸ that the Congressional ban

³ *Western States*, *supra* note 2

⁴ *See*, for example, our July 30, 2002 complaint to the FDA alleging that some of Ben & Jerry's ice cream labels are false and misleading because they assert that the product is "All Natural" even though the ingredient statement indicates that the product contains artificial flavorings and other man-made ingredients.

⁵ 447 U.S. 557 (1980). The legal standard in such cases is that the government must show that the restriction serves a substantial governmental interest, directly advances that interest, and is not more extensive than is necessary to serve that interest.

⁶ "Although several members of the Court have expressed doubts about the *Central Hudson* analysis and whether it should apply in particular cases. . . . *see e.g., Greater New Orleans Broadcasting Assn., Inc. v. United States, 44 Liquormart, Inc. v. Rhode Island.*" (Citations omitted)." *Thompson v. Western States*, 122 S.Ct. at 1504.

⁷ *Lorillard Tobacco v. Reilly*, 533 U.S. 525 (2001).

⁸ *Western States*, *supra* note 2.

on the advertising of compounded drugs⁹ violates the First Amendment. The Court agreed that Congress had an important interest in ensuring that drug compounders were not engaging in the large-scale manufacture of drugs. But the court held that using advertising as a “proxy” for large-scale manufacturing was too restrictive when other means of accomplishing the same end were possible.¹⁰

The *Western States* decision concerned a specific statutory provision for drugs and does not directly apply to the FDA’s regulation of foods or dietary supplements; moreover, it does *not* hold that the First Amendment prevents the FDA from prohibiting product labels and ads from containing certain information. Unfortunately, the FDA seems intent on using the *Western States* case to justify a wholesale revision of its regulatory policies for all products, without involving Congress in the outcome of its actions. The course of action chosen by the Agency is thus inappropriate and suspect.

Prior to undertaking any revisions of its regulations for food and dietary supplement health claims on First Amendment grounds, the FDA should request that the National Academy of Sciences follow-up on its recently released report entitled *Evolution of Evidence for Selected Nutrient and Disease Relationships*.¹¹ That report concluded that industry and the FDA should be cautious about using claims based on preliminary results because it is difficult to predict whether such claims will be confirmed, and further testing may reveal unexpected consequences.

⁹ “Drug compounding is a process by which a pharmacist or doctor combines, mixes or alters ingredients to create a medication tailored to the needs of an individual patient.” *Id.* at 1500.

¹⁰ *Id.* at 1505.

¹¹ National Academy of Sciences, Institute of Medicine, *Evolution of Evidence for Selected Nutrient and Disease Relationships* (2002).

The NAS urged the FDA and industry to be cautious about the use of claims based on preliminary evidence because it is not possible to predict which preliminary claims will be confirmed by later studies. The IOM explained that “[c]laims 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.”¹² 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 large doses of beta-carotene could reduce the risk of lung cancer in smokers, three clinical trials later demonstrated that high doses of beta-carotene actually increase the risk of lung cancer in smokers.¹³

The FDA needs NAS’s guidance on whether qualified claims based on less than “significant scientific agreement”¹⁴ serve the public interest. The Agency must also thoroughly study whether disclaimers of the type discussed in Sections I-3 to I-6 of the *Federal Register* notice will prevent misbranding as required by section 403(a) of the Federal Food, Drug and Cosmetic Act.

After the NAS report is complete, the Agency should hold a public meeting to discuss these issues. The FDA should invite members of a variety of organizations, including consumer and medical groups, as well as individuals or organizations with expertise in the public health implications of the commercial speech doctrine. The FDA should then submit to Congress a

¹² *Id.* at 58.

¹³ *Id.* at 6.

¹⁴ FDCA § 403(r)(3)(B), 21 U.S.C. § 343(r)(3)(B).

report of the meeting with any recommendations concerning changes in the Agency's regulations or policy, prior to implementing any of the recommendations.

Despite CSPI's misgivings about the Agency's rush to move forward without taking these steps and the overall nature of this proceeding, we will nonetheless respond to several requests for comment specifically dealing with food and dietary supplement regulation. These matters are raised by Questions 3, 4, and 8 in the *Federal Register* announcement. Each will be discussed in turn.

"Question 3"

A. May FDA distinguish claims concerning foods from those relating to supplements taking into account limits on claims ?

Yes.¹⁵ The decision in *Pearson v. Shalala*¹⁶ applies to supplements only. In its decision, the Court of Appeals invalidated FDA regulations on the grounds that the First Amendment prevented the Agency from prohibiting health claims for dietary supplements that do not meet the "significant scientific agreement" standard unless it first considered whether the use of a qualifying statement in conjunction with the claim would prevent consumer deception.

Congress has long maintained a distinction between supplements and conventional foods. For example, in enacting the Nutrition Labeling and Education Act (NLEA), Congress gave the FDA authority to apply different standards and procedures with respect to the approval of health claims for dietary supplements and foods.¹⁷ For dietary supplement health claims, Congress did

¹⁵ Ideally, health claims for both foods and dietary supplements should be supported by "significant scientific agreement" based on the totality of publically available scientific evidence.

¹⁶ 164 F.3d 650 (D.C. Cir. 1999).

¹⁷ 21 U.S.C. § 403(r)(5)(D).

not mandate a specific standard, but rather left the decision to the Agency. In the case of foods, however, Congress specifically mandated that health claims be supported by “significant scientific agreement.” Congress enacted this provision based on a rich legislative record demonstrating that the marketplace was rife with unfounded claims. The Court of Appeals in *Pearson* did not have the benefit of this legislative record, as the case involved a challenge to only FDA’s regulations for dietary supplement health claims.

Congress continued distinguishing between dietary supplements and foods four years later when it enacted the Dietary Supplement Health and Education Act (DSHEA). That law, for example, permits dietary supplements to make structure/function claims, which foods have been permitted to make since 1938. However, unlike foods, dietary supplements are subject to a number of procedural requirements and must also include a disclaimer that the FDA has not reviewed the claims.

Still again, in 1997, Congress passed the Food and Drug Administration Modernization Act (FDAMA), which authorizes health and nutrient content claims based on authoritative statements for conventional foods, but did not include similar language for dietary supplements.

Similarly, the FDA has distinguished between food and dietary supplements when designing and enforcing regulatory programs for label claims. For example, if a structure/function claim is made for a food product, the FDA requires that the claim relate to the nutritive value of the substance that is the subject of the claim.¹⁸ Such requirements do not apply to dietary supplements. All of these actions, by the courts, Congress, and the FDA indicate that there are sound reasons for distinguishing between claims for dietary supplement and foods and that there is

¹⁸ 62 Fed. Reg. 49859-60 (Sept. 23, 1997). The FDA does not apply the same requirements to dietary supplements.

no basis for expanding the holding in *Pearson* to other product categories.

B. What must an administrative record contain to sustain or deny claims on food labels?

In *Pearson v. Shalala*, the FDA was ordered to “explain what it means by significant scientific agreement or, at minimum, what it does not mean.”¹⁹ In *Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements*,²⁰ FDA responded to the order and described the quality and quantity of scientific evidence that must be available to support the approval of a health claim.

It is noteworthy that the *Pearson* court also held that FDA does not have to issue a “comprehensive definition all at once,” explaining that the Agency is entitled to proceed on a case-by-case basis.²¹ We believe that the FDA Guidance document and the three qualified health claims that the Agency has approved since the *Pearson* decision represent a good start. We agree with the Court of Appeals that this matter should continue to be decided case-by-case because the quality and quantity of scientific evidence appropriate for the approval of a health claim differs depending on the nutrient and disease relationship that is involved.

With respect to structure/function claims, the administrative record should contain a thorough discussion of why a claim meets or does not meet the applicable substantiation standard for such claims. The problem is that the FDA has never articulated a substantiation standard for structure/function claims. There is no basis for alleging, as some members of the industry have done, that structure/function claims should be supported by any less scientific evidence than health

¹⁹ *Pearson*, 164 F.3d at 660.

²⁰ December 22, 1999, available at <www.cfsan.fda.gov/~dms/ssaguide.html>.

²¹ *Pearson*, 164 F.3d at 660.

claims. As the General Accounting Office has found,²² there is evidence that consumers do not distinguish between health claims and structure/function claims. Thus, there is no reason to sanction a lesser evidentiary standard for the latter category of claims. If anything, structure/function claims should be required to meet a higher evidentiary standard than health claims considering that the Agency has an opportunity to review proposed health claims before they are made but has no similar pre-market approval process in place for structure/function claims. We believe that structure/function claims should be limited to universally recognized statements of fact. A high substantiation standard is appropriate in light of the absence of a pre-market approval system.

To deny a health claim for a food, the FDA must determine that the claim is not supported by “significant scientific agreement” as set out in its Guidance document. To deny a health claim for a dietary supplement, the Court in *Pearson* has placed an additional responsibility on FDA to demonstrate that the use of a disclaimer or qualifying statement in conjunction with a claim not supported by “significant scientific agreement” would not sufficiently protect consumers from being misled.

Some companies view this decision as a “green light” to make health claims based on preliminary studies and inconclusive results. The Court of Appeals, however, did not require that the FDA must approve all health claims accompanied by a disclaimer or qualifying statement. Rather, that court required that once the FDA determines that a suggested claim is not supported by “significant scientific agreement,” it must then evaluate whether a disclaimer could turn an otherwise unsubstantiated or misleading claim into a truthful and non-misleading statement. That

²² General Accounting Office, *FOOD SAFETY: Improvements Needed in Overseeing the Safety of Dietary Supplements and Functional Foods* (GAO/RCED-00-156) (July 2000) at 23.

is the FDA's only obligation.

Moreover, under the *Pearson* decision, the FDA need not allow a health claim if:

permitting the claim would threaten consumer health or safety;

scientific evidence supporting a claim is outweighed by evidence that is qualitatively or quantitatively superior; or

empirical evidence demonstrates that a disclaimer is insufficient to protect consumers from deception.

Thus, to deny a health claim for dietary supplements, the administrative record must include evidence demonstrating that one or more of the above points is true or that a disclaimer or qualifying statement would not prevent consumer deception.²³

C. How can information [claims] best be presented in a succinct but non-misleading fashion?

The FDA has done a reasonable job in trying to balance the competing needs of authorizing health claims that are scientifically valid, truthful, not misleading, and at the same time are succinct and to the point. Despite protestations from the food and dietary supplement industries that FDA authorized claims are too wordy and cumbersome to use, the fact remains that numerous companies have successfully utilized such claims in marketing. Many of the 17 claims that the FDA has authorized have been used in the marketing of nationally distributed, brand name products such as Green Giant brand frozen vegetables, Campbell Soup Company products, Kellogg breakfast cereals, Quaker Oatmeal, General Mills breakfast cereals, Tropicana orange juice, Benecol and Take Control spreads, Tums Calcium supplements and numerous other products.

Additional consumer research is needed to demonstrate how well particular claims are

²³ A more thorough discussion of the *Pearson* decision appears in Attachment 1.

communicated. FDA should conduct such research before the Agency changes any of its regulations or enforcement policies governing this area.

D. To what extent do assertions in claims need qualifications or disclaimers added to the label to avoid any misconceptions that consumers may draw?

1. Health claims/Qualifying statements

Disclaimers advise consumers that the FDA has not reviewed the safety or effectiveness of a product. Qualifiers are used to clarify the scientific status of a claim. Any approved health claim for dietary supplements not subject to significant scientific agreement needs to be qualified to clarify the scientific uncertainty behind the claim. The experience of other regulatory agencies with requiring qualifications and/or disclaimers, however, demonstrates that this approach is fraught with difficulties.

The Federal Trade Commission (FTC), which regulates the advertising of most products, including foods and dietary supplements, has required certain companies to include “affirmative disclosures” when it has determined that the disclosure of additional information is necessary to eliminate consumer deception.²⁴ An example of this type of disclosure is “batteries not included.” This remedy is also employed when the contents of an ad are vague or ambiguous in a material way, thereby requiring clarification.²⁵ The requirement that ads for weight loss carry a disclosure that “results are not typical” exemplifies this type of statement.

Some researchers have questioned the effectiveness of affirmative disclosures. For example, the FTC’s own Bureau of Consumer Protection and Bureau of Economics commissioned

²⁴ See, e.g., *Removatron Int’l Corp. v. FTC*, 884 F2d 1489 (1st Cir. 1989).

²⁵ George Eric Rosen and Peter Eric Rosen, 2 *The Law of Advertising* §18.04[1] (1999) (*footnotes and citations omitted*).

consumer research on “affirmative disclosures” in food advertising that made health claims.²⁶ The FTC attempted to determine which type of disclosures should accompany health claims not supported by “significant scientific agreement.” It tested different types of disclosure language to determine which was best able to help consumers understand the range of levels of evidence in support of claims. It found that only “strong disclaimers” – explicit references to inconsistent study results or ongoing scientific debate such as “it’s too early to tell for sure” or “longer term research is needed” – had the greatest impact on consumer perceptions of the level of proof underlying a health claim.²⁷

Yet, the vast majority of food and dietary supplement advertisements that make health claims do not contain such disclosures. Instead, the food and dietary supplement industries typically state that there is “promising research” or “studies show. . . .”²⁸ The ads do not indicate that the research is only preliminary and further research must be conducted to support the results. Clearly, this type of qualifying statement is insufficient to protect consumers from being misled by health claims not supported by significant scientific agreement. The FTC has not brought a single case to enforce its policy on this matter, and there has been little compliance with it. This leaves

²⁶ In its “Enforcement Policy Statement on Food Advertising,” 59 Fed. Reg. 28388 (1994), the FTC states that it will allow two general categories of health claims in food advertisements: (1) claims that had been approved for product labels by FDA (i.e. claims that the Agency had determined were supported by “significant scientific agreement”); and (2) claims that were not approved by FDA *if* they are “expressly qualified to convey clearly and fully the extent of the scientific support.” *Id.* at 28394.

²⁷ *Dennis Murphy, et. al., Generic Copy Test of Food Health Claims in Advertising*, (FTC. Nov. 1998) at E-8 to 9.

²⁸ For example, an ad for Campbell’s Tomato Soup proclaims “Recent studies are showing that a diet rich in tomato products is associated with the reduced risk of certain types of cancers. . . .” Campbell’s TV ad, “Woman in Kitchen with Wallpaper, shown 1/20/00, *available from Video Monitoring Services of America*. (Attachment II).

open the question as to whether the FDA should base changes in its regulatory policies on unenforced and questionable FTC policy.

We urge the FDA to review other regulatory areas where disclosures and disclaimers are employed and to carefully examine existing research before it considers more widespread use of a disclosure/disclaimer approach which, in practice, has had a checkered history filled with dubious outcomes

2. Structure/function claims - Disclaimers

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.”²⁹

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 evidently were unaware of the lack of substantiation of the claims because they had either never read the disclaimer or had simply misread it to say that FDA had in fact evaluated the claim.³⁰

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

²⁹ FDCA § 403(r)(6)(C), 21 U.S.C § 343(r)(6)(C)

³⁰ 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).

respondents in the study indicated that they had either never seen the disclaimer or didn't know if they had ever seen it (59 percent).³¹

Numerous other disclosures and disclaimers, in addition to the DSHEA disclaimer, 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 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.³² Moreover in its *Generic Copy Test*, the FTC 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."³³

E. Is there a basis to believe that consumers approach conventional foods and dietary supplements differently?

Yes. Dietary supplements are viewed by many consumers as a way to promote health while food to most people is simply a means of sustenance. Approximately 60 per cent of Americans take some form of a dietary supplement every day.³⁴ Consumers who take supplements

³¹ AARP Public Policy Institute, *Dietary Supplements and Older Consumers Data Digest* 66 (Dec. 2001).

³² *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).

³³ Press Release, "FTC Releases the Food Copy Test Results" (Nov. 18, 1998).

³⁴ Dept. of Health and Human Services, Office of Inspector General, *Adverse Event Reporting for Dietary Supplements: An Inadequate Safety Valve* (April 2001) at i.

may be more health conscious 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. Practicably all foods are safe for children over two years of age to consume. In contrast, only some dietary supplements are safe for children to consume. In sum, there is every reason to believe that consumers approach the purchase of foods and dietary supplements differently.

“Question 4” — Should disclaimers be required to be in the same (or smaller or larger) size of type and given equal prominence with claims?

First, we assume that the question refers to both disclaimers and qualifiers. The distinction is important because disclaimers advise consumers that the FDA has not reviewed the safety or effectiveness of a product. Qualifiers are used to clarify the scientific status of a claim. It is important that consumers see the entire claim in context. For this reason, it is *essential* that the disclaimers and qualifiers appear in close proximity to the claims, have equal prominence, and be in the same size of type.

“Question 8” — Do FDA’s speech-related regulations advance the public health concerns they are designed to address?

The implementation of the NLEA has been very successful. Surveys demonstrate that there is widespread use of the Nutrition Facts label and that consumers who use the label consume a lower percentage of calories from fat compared to those that do not use the label.³⁵ Many new, lower fat products have been introduced because of the fact that consumers can now determine the nutritional value of products before making a purchasing decision.

FDA’s health claims regulations have also been effective. Prior to the passage of the

³⁵ Marian L. Neuhouser, *et. al.*, *Use of food nutrition labels is associated with lower fat intake*, *Journal of the American Dietetic Assoc.* (Jan. 1999) at 45.

NLEA, frivolous claims led *Business Week* to proclaim on its cover “Health Claims for Foods are Becoming Ridiculous.”³⁶ Today, the marketplace is relatively free of misleading health claims on the labels of food products and major manufacturers now use FDA-approved claims.

In contrast, the passage of DSHEA, which permitted the use of structure/function claims on dietary supplements, has led to a market place free-for-all of misleading labels that has injured both consumers and the industry. The absence of a pre-market approval system and strong substantiation standard for such claims has resulted in products claiming to cure almost every ailment under the sun. Ironically, the greater regulatory freedom provided by DSHEA, now demanded by the food industry as a First Amendment right, has not served either consumers or the supplement industry very well. There have been thousands of reports of consumers injured by dietary supplements, and industry sales have declined in light of the consumers’ experiences with the product category as a whole.

According to one trade advertisement appealing for help to keep the industry alive,³⁷ many companies are facing possible bankruptcy because consumers have become disillusioned with outrageous claims that don’t pan out. The experience of the supplement industry demonstrates that regardless of the commercial speech freedoms that may be granted to companies by the judiciary, the exercise of such freedoms often do not make commercial sense.

³⁶ *Business Week*, *Can Cornflakes Cure Cancer?* October 9, 1989. See Attachment III.

³⁷ Advertisement of Dietary Supplement Education Alliance, *Whole Foods Sourcebook* 2002. The ad states “[a]fter nearly four years of unprecedented positive growth in the natural products industry we now have experienced 17 consecutive months of ‘negative growth.’” (Attachment IV).

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Bruce Silverglade", written over a horizontal line.

Bruce Silverglade
Director of Legal Affairs

A handwritten signature in cursive script, appearing to read "Ilene Ringel Heller", written over a horizontal line.

Ilene Ringel Heller
Senior Staff Attorney

Attachment I

I. The FDA is not obligated to consider using the disclaimer approach when a preliminary health claim raises health and safety concerns.

At the outset, it should be emphasized that the Court's overall holding in *Pearson v. Shalala* was premised on the basis that the supplements at issue in the case do not "in any fashion threaten consumers' health and safety."¹ However, there has been a steady stream of reports concerning the hazards of dietary supplements. The Washington Post, for example, ran this front page article that proclaimed "Herbal Products Boom Take Human Toll."² The government apparently did a poor job of bringing this type of information to the Court's attention, and the Court simplistically assumed that supplements in general posed no hazard. In light of this naive assumption, the relevance of the Court's primary holding is quite limited. As the Court noted, "the government may have more leeway in choosing suppression over disclosure as a response to the problem of consumer confusion where the product *affects health*."³ Health claims for dietary supplements that are not supported by significant scientific agreement can have an adverse impact on health in several different ways.

A. The FDA need not consider using the disclaimer approach where claims relate to essential bodily organs or serious health conditions.

Under the Court's opinion, the FDA need not and should not consider using the disclaimer approach if a proposed health claim not based on significant scientific agreement pertains to an

¹ 164 F.3d at 660.

² Guy Gugliotta, *Health Concerns Grow Over Herbal Aids; As Industry Booms, Analysis Suggests Rising Toll in Illness and Death*, Wash. Post, Mar. 19, 2000, at A1, A22.

³ *Pearson*, 164 F.3d at 659 (emphasis added).

essential organ or a serious health condition. This would include, for example, claims regarding the heart, lung, brain and liver. This exception to the Court's holding also pertains to claims regarding serious health conditions including risk factors for cancer and heart disease, as well as asthma, birth defects, diabetes, HIV, and Alzheimer's disease. The Court recognized that in situations where either consumer health or safety is involved, claims supported by preliminary scientific evidence would be inappropriate even if accompanied by a disclaimer.

The Court's holding on this point is well-grounded. For example, in the 1990's beta carotene supplements were being promoted by the supplement industry as substances that might reduce the risk of cancer. Preliminary epidemiological studies had demonstrated a promising link between the consumption of beta carotene rich foods and a reduced risk of cancer. Clinical studies conducted afterwards, however, showed strong evidence of *no* benefit from beta carotene supplements and indicated that the use of such products by smokers might actually increase their risk of lung cancer.⁴ Additional clinical studies funded by the National Institutes of Health confirmed these findings and led the researchers to discontinue the studies.⁵

Therefore, it is essential that claims that a substance can reduce the risk of a serious disease like cancer should only be permitted where significant scientific agreement exists; under the Court's holding, the FDA is not obligated to permit such claims on the basis of preliminary evidence.

⁴ National Cancer Institute, Press Release, *Beta Carotene and Vitamin A Halted in Lung Cancer Prevention Trial*, Jan. 18, 1996.

⁵ *Id.*

B. The FDA need not consider using the disclaimer approach when it is foreseeable that consumers may, based on a preliminary claim, forego a proven dietary or medical therapy in favor of a dietary supplement that may or may not be beneficial to health.

As the Court recognized, the FDA may choose to suppress claims not supported by significant scientific agreement instead of permitting them with a disclaimer in situations where a supplement “affects health.”⁶ Preliminary claims for dietary supplements that may or may not be beneficial can cause injury to health if consumers choose them over proven dietary or medical therapies. Thus under the Court’s holding, the FDA is not obligated to permit preliminary health claims with a disclaimer if the claim would lead consumers to rely on an unproven dietary supplement instead of a proven dietary or medical therapy.

A survey conducted by *Prevention Magazine* with technical assistance from the FDA estimates that consumers often substitute unproven dietary supplements for proven therapeutic approaches even in the absence of preliminary health claims. According to this survey, 22.8 million consumers used dietary supplements *instead* of prescription medicine, and 30.3 million used herbal remedies *instead* of an over-the-counter drug. Thus, it is evident that supplements -- which largely have not been tested for safety and efficacy -- have already replaced many prescription and over-the-counter drugs that have been demonstrated to be safe and effective. The use of preliminary health claims would surely exacerbate this trend and cause additional injury to consumer health. As the Prevention survey concluded: “Already, an estimated 11.9 consumers have experienced adverse reactions from using herbal remedies, and 6.5 million have had problems of this kind when

⁶ *Pearson*, 164 F.3d at 659.

using specialty supplements.”⁷

To permit health claims to be made on a basis other than significant scientific agreement presents an unnecessary and unjustified threat to consumer health, especially when the claim may encourage consumers to forego a proven dietary or medical treatment in favor of a supplement that may or may not work. In such situations, the use of a disclaimer approach is an insufficient means of protecting consumer health and safety, and, under the Court’s opinion, the FDA may instead prohibit the claim completely.

C. The FDA need not consider using the disclaimer approach when consumers, based on their own observations, cannot determine whether a claim is true.

Consumers who rely on preliminary health claims and take dietary supplements promoted for conditions that are difficult to self-diagnose have no way of knowing whether the products are working. The use of preliminary health claims not supported by significant scientific agreement is particularly dangerous in such cases because they may lead consumers to rely on treatments that may not be effective. The Court’s decision in *Pearson* does not require the FDA to approve preliminary claims with a disclaimer if the health and safety of consumers are threatened as they are in this situation.

II. The FDA is not obligated to consider the disclaimer approach when scientific evidence supporting a claim is outweighed by quantitatively or qualitatively superior evidence.

In *Pearson*, the Court stated that the FDA can prohibit preliminary health claims where the scientific evidence in support of the claim is outweighed by the evidence against the claim, or

⁷ *Prevention Magazine’s National Survey on Self-care Reveals 158 Million Consumers Use Dietary Supplements for Their Health and Spend Approximately \$8.5 Billion Each Year; Survey Also Reports That Widespread Use of Dietary Supplements May Cause Public Health Problems*, PR Newswire, Feb. 25, 2000.

where the evidence supporting it is qualitatively weaker than the evidence against it. The Court's decision thus calls on the FDA to weigh and evaluate the scientific evidence in support of a claim. If studies in support of a claim are qualitatively weaker than studies siding against a claim, then the claim may be prohibited. Also, if the number of studies demonstrating that a claim is invalid is larger than the number of studies supporting the claim, the FDA may prohibit the claim completely. We believe this exception to the Court's primary holding is very broad and will apply to many of the decisions that the FDA will face in this area.

III. The FDA is not obligated to consider permitting preliminary health claims with a disclaimer when empirical evidence shows that the disclaimer is insufficient to protect consumers from deception.

The Court in *Pearson* stated that disclaimers would not be required where “empirical evidence that disclaimers similar to the ones . . . suggested. . . [by the court] would bewilder consumers and fail to correct for deceptiveness. . . .”⁸

The FDA should thus conduct research so that it can obtain empirical evidence demonstrating when disclaimers do not prevent consumer deception caused by health claims that fail to meet the significant scientific agreement standard. A study conducted by the FTC on health claims in advertising leads to the conclusion that most disclaimers currently in use in advertising are insufficient to protect consumers.⁹ The FDA should conduct its own research on food and

⁸ *Pearson*, 164 F.3d at 659-660.

⁹ *E.g.*, Federal Trade Commission, *Generic Copy Test of Food Health Claims in Advertising*, Nov. 1998. For example, the FTC found that where disclaimers were used to inform consumers that a product high in one beneficial nutrient also contained high levels of another nutrient that could increase the risk of a diet-related disease, almost half of those surveyed “apparently misconstrued the dietary warning as a favorable commentary on the quantity of sodium or saturated fat in the advertised products.” *Id.* at E. 3-4.

dietary supplement label claims.

We note that under the Supreme Court doctrine in this area, a disclaimer approach is traditionally used to provide consumers with additional information to remedy a deceptive claim and help them choose between products or services. In the leading case, *Zauderer v. Office of Disciplinary Counsel*, an attorney had advertised that he accepted cases on a contingency basis with “no cost” to the client. The Supreme Court upheld an Ohio Bar rule requiring the lawyer to disclose that clients were still responsible for paying costs if the litigation were unsuccessful.

Similarly, in the dietary supplement area, a disclaimer providing additional information would be appropriate where there was significant scientific agreement that a substance produced a desired effect, but that other factors played an important role as well. For example, if the truthfulness of a health claim for an herbal substance is dependent upon consuming it with a diet low in fat, then that disclosure would be material to consumers.

The examples of the disclaimers suggested by the *Pearson* court, however,¹⁰ do not provide consumers with any useful additional information to help them evaluate the safety and health benefits of a supplement. Simply informing consumers that the scientific evidence is inconclusive and/or that the FDA has not approved a claim merely constitutes a disclaimer of responsibility; such statements do not provide consumers with additional useful information that remedies an otherwise misleading claim.¹¹ There is a vast difference between merely disclaiming responsibility and disclosing useful information that qualifies an otherwise deceptive statement.

¹⁰ “The FDA does not approve this claim” or “the evidence in support of this claim is inconclusive.” *Pearson* at 659.

¹¹ David C. Vladeck, *Devaluing Truth: Unverified Health Claims in the Aftermath of v. Shalala*, 54 Food and Drug L.J., 535-554 (1999).

While the Court expressed confidence in the specific wording of the disclaimers that it suggested the FDA utilize, it did not “rule out the possibility”¹² that its suggested approach would “bewilder consumers and fail to correct for deceptiveness.”¹³ It is, therefore, incumbent upon the FDA to conduct the necessary consumer research and resolve the Court’s uncertainty about its holding.

¹² *Pearson* at 660.

¹³ *Id.* at 659-60.



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PRODUCT Campbell's Classics
MARKET Network
PROGRAM Days Of Our Lives
CODE # 0001-05646
TITLE Woman In Kitchen With Tomato Wallpaper

LENGTH :30
STATION NBC
DATE 01/20/00
TIME 1:33 PM



(MUSIC IN) MALE ANNCR: Recent studies are showing



that a diet rich in tomato



products is associated with the reduced risk



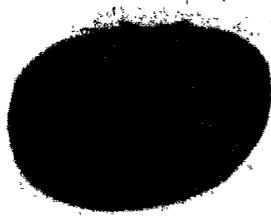
of certain types of cancers, and a hot bowl of



Campbell's Tomato Soup



is one of the most delicious ways



for you to enjoy the goodness of juicy, vine-ripened tomatoes,



at a pick at the peak of perfection. Want something good for you that tastes good too?

**WE HAVE A
SOUP
FOR THAT**

We have a soup for that:

**WE HAVE A
SOUP
FOR THAT**

(GRFX: DIFFERENT TYPE OF SOUPS FLASH)

**WE HAVE A
SOUP
FOR THAT**

Campbell's Tomato Soup.

**WANT
SOUP
FASTER?**

Want soup even faster? Try Campbell's ready-to-serve Tomato Soup. It's even more convenient. (MUSIC OUT)

ATTACHMENT II

ALSO AVAILABLE ON VIDEO CASSETTE

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BusinessWeek

OCTOBER 9, 1989

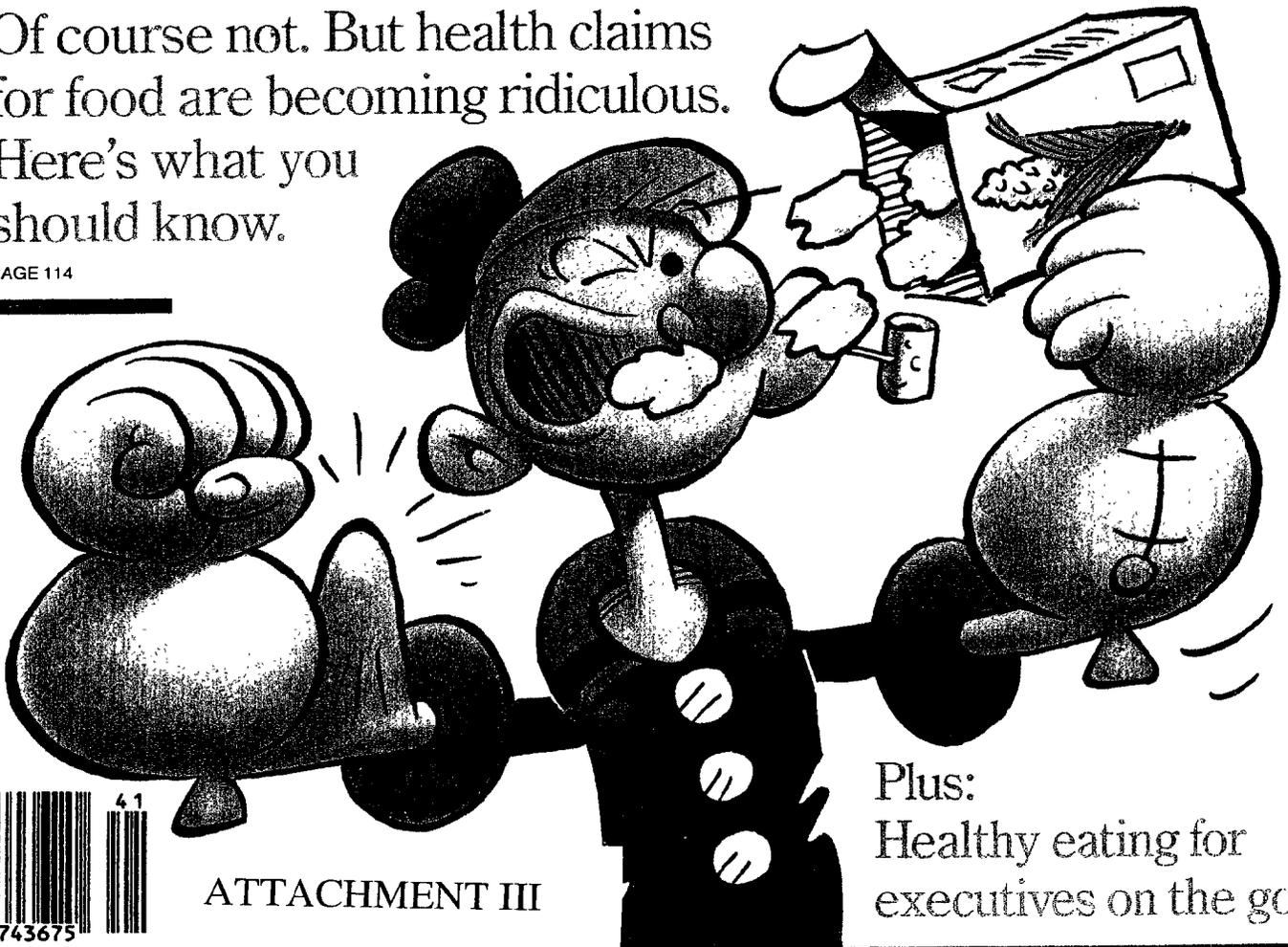
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CAN CORN FLAKES CURE CANCER?

Of course not. But health claims for food are becoming ridiculous. Here's what you should know.

PAGE 114



Plus:
Healthy eating for
executives on the go



ATTACHMENT III

THE GREAT AMERICAN

HAVE FOOD COMPANIES GONE OVERBOARD IN ADOPTING THAT OLD PARENTAL

Want to avoid a heart attack? Eat olive oil and oat bran—they'll lower your cholesterol. Need to strengthen your bones? Drink calcium-fortified orange juice. Want to fight off cancer? We've got just the cereal for you.

These days, the supermarket food aisles look like a modern medicine show. With the American public increasingly anxious about diet and disease, food companies are claiming health benefits everywhere. They are finding previously hidden virtues in old products and introducing hundreds of new ones to fit every imaginable nutritional niche. Fully 30% of the \$3.6 billion in annual U.S. food advertising now includes some type of health message.

The hodgepodge of medical pronouncements, technical terminology, and advertising hyperbole has left consumers scanning the shelves in bewilderment. As nutritionists argue over wheth-

er most people really need to cut cholesterol in the bloodstream (page 128), some cookie makers are touting their cholesterol-free but usually high-fat, high-calorie products as healthy food. And while scientists debate the role of fiber (page 124) in preventing heart attacks—or is it colon cancer?—food makers are stuffing oats and bran into potato chips and bread.

Critics complain that the food industry's sudden emphasis on health is nothing more than a marketing gimmick. They point out that while high-fiber cereals and low-fat dairy products are being pushed into the spotlight, no one seems to be talking about the benefits of fresh vegetables and beans—products not backed by giant food packagers.

Some nutrition advocates and health-care watchdogs say the messages aren't so bad, even if they're incomplete. By raising public awareness about diet and health, they say, the claims may be help-

ing to change what Americans eat. But even a few industry executives admit to misgivings about using health pitches to sell food: "It's got to be here to stay if it sells products," says a top food-company executive. "But it's really a mixed bag because the consumer is so foolable." Adds Richard A. Zimmerman, chief executive of Hershey Foods Corp., which makes pasta as well as its well-known candies: "I think you mislead more people than you educate."

OATSY COLA? The tactics have clearly hit a consumer hot button, though. Cereal sales, for example, have been energized by a series of highly publicized reports suggesting that high-fiber diets may reduce the risk of some cancers. Most recently, a National Cancer Institute study showed that wheat bran may shrink existing precancerous polyps of the colon in some people. Since 1987, cereal sales

ILLUSTRATIONS BY ROBERT ZIMMERMAN, PHOTOGRAPHS BY PETER ARDITO



HEALTH PITCH

REFRAIN: 'EAT IT, IT'S GOOD FOR YOU'?

have risen 22%, to \$6.6 billion. "The message is getting through," says Kellogg Co. Chairman William E. LaMothe.

Oats, in particular, got a boost from evidence that oat bran may lower levels of blood cholesterol and, in turn, the risk of heart disease. So far this year, sales of cereals containing oat bran have risen 70% by volume. A shelfful of cereals new and old now blare their oat bran contents at shoppers, and products ranging from blueberry muffins to bagels, pasta, and, yes, potato chips, are feeling their oats, too. In a recent survey conducted by Lempert Co., an ad agency, 74% of Pepsi drinkers said they would switch to Coke if it had oat bran

in it. (Coca-Cola, are you listening?)

Competitive pressures in the slow-growth food industry are likely to drag into the game even those marketers who have misgivings about health pitches. "I don't own this place," says one food-company executive. "When the chairman says, 'Why don't we have 87 products like this?' I'll roll them out as fast as I can." Adds Robert J. Gillespie, president of CPC International Inc.'s Best Foods: "Without guidelines, we almost run the risk of going back to the snake-oil era."

HYPE HAZARDS. It all started with a precedent-shattering move by Kellogg in 1984 when it won approval from the National Cancer Institute to state in ads and on boxes for its All-Bran cereal that the NCI believes "a high-fiber, low-fat

diet may reduce the risk of some kinds of cancer."

The packages violated a decades-old rule against health claims for food. But while the Food & Drug Administration, which oversees food labeling, wasn't happy, it wasn't willing to use its power to declare the cereal an illegal drug and seize it. Nor was it willing to attack a claim approved by the NCI, a fellow government agency. And the FDA's attempts since then to establish new guidelines on health claims have been thwarted by free-marketers at the Office of Management & Budget (BW—Sept. 25). Hear-



NO MIRACLE
Cholesterol-free dressings often have the same number of calories and the same fat content as the regular stuff.



HOW COOKIES CRUMBLE
Cookies and crackers made from vegetable oil have no cholesterol. But they may contain partially hydrogenated oils, adding saturated fat.



A BETTER CRISCO, BUT
Crisco is taking out the palm oil. But it's still made from hydrogenated oils. So it's 26% saturated fat.



LOW-CAL BUT FATTY
Some diet foods are low-calorie mostly because the portions are small. They may be high in cholesterol or sodium, and they often get far more than 30% of their calories from fat.

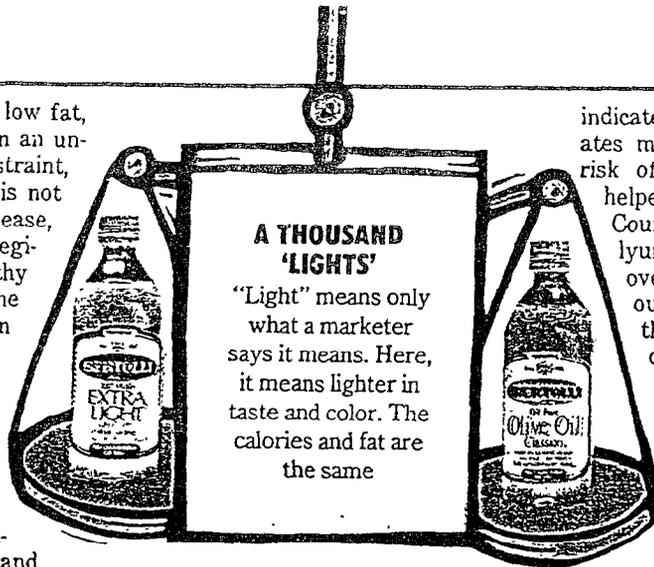
Choice frozen dinners that have low fat, cholesterol, and sodium levels. In an unusual display of marketing restraint, the packages say: "This dinner is not a remedy or cure for heart disease, and is only one part of a daily regimen for healthy living." Healthy Choice already claims 22% of the premium frozen dinner market in that half of the nation where it is sold. Stouffer Foods Corp., which already offers its Lean Cuisine to calorie counters, is launching a similar line called Right Course.

Kraft General Foods Group, the nation's largest food company, has added a raft of low-fat and cholesterol-free products, such as Breyer's Light ice milk and lower-calorie versions of its cream cheese, mayonnaise, and sour cream. Borden Inc., too, has introduced a slew of products that include a skim milk formulated to taste as if it had more fat. More than half of the 800 dairy products launched industrywide last year were nonfat or low-fat, according to *Dairy Foods* magazine.

Some marketers may be a bit too eager to proclaim how little their products have of some nasty substance, though. Take the game of portion sizes. Many canned-soup makers have changed the suggested serving sizes on their labels from 2 per can to 2½. The can isn't any bigger, so the portions are now actually 20% smaller. That reduces the numbers for fat, calories, and salt by the same proportion, even though the soup itself hasn't changed. Serving sizes of diet soft drinks also shrank, from 12 to 6 ounces. An FDA official notes that only at the smaller size do the drinks qualify for "very low sodium" labeling.

JUDGING BRANDS. Similarly, Kraft General Foods says that its Philadelphia Brand cream cheese has only half the calories of butter or margarine—but that's for equal amounts. A typical schmear of cream cheese is twice the size of a normal serving of butter, according to FDA guidelines.

Despite such labeling legerdemain, some public in-



A THOUSAND 'LIGHTS'

"Light" means only what a marketer says it means. Here, it means lighter in taste and color. The calories and fat are the same

terest groups say they're pleased that so much attention is being paid to health. Says Darlene A. Dougherty, president of the American Dietetic Assn.: "Because I see it as increasing the public's awareness, I see it as a positive." By next February, the American Heart Assn. will even begin putting a seal of approval, called the HeartGuide, on products it has evaluated, including oils and frozen or canned foods.

Nevertheless, it's often difficult for even the savviest consumer to use general notions of diet and health to judge specific brands. That's not entirely the fault of marketers, because scientific advice is constantly changing and often contradictory. Experts had long recommended diets low in saturated fats and high in polyunsaturates, for example. Consumption of saturated fat is linked to higher blood cholesterol levels, which along with smoking and high blood pressure is one of three modifiable risk factors for cardiovascular disease. That meant that animal fats, hydrogenated fats, and tropical oils such as coconut and palm were out, while corn and sunflower oils were in.

Some animal re-

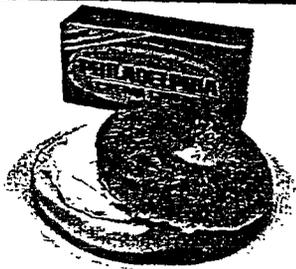
search indicates that high levels of polyunsaturates may be associated with a greater risk of certain kinds of cancer. That helped lead the National Research Council to recommend limiting polyunsaturates to less than 10% of overall calories. Meanwhile, monounsaturates—something 73% of the public has never heard of, according to the FDA—suddenly are being portrayed as the hero in the bunch. Some research has found that if it replaces saturated fat, monounsaturated fats—found in olive and rapeseed oil—may cut the "bad" cholesterol that forms arterial plaque without decreasing the "good" cholesterol that helps dissolve plaque.

This recent discovery that polyunsaturates may cause problems demonstrates just how treacherous the shifting sands of nutrition research can be. While the general injunction to eat a variety of foods is as true as ever, today's specific advice obviously could be outdated tomorrow.

LIGHT LOGIC. Marketing tactics don't exactly make matters clearer. Take the healthy, dietetic-sounding word "light," which has little legal or regulatory meaning. Two leading marketers of olive oil, Bertolli and Filippo Berio, have come up with "light" products more attuned to the U.S. market. But these oils are lighter only in color and taste, not in calories or fat. The companies say the products are intended only to address many consumers' dislike of strong-tasting olive oil. And Sara Lee Corp. Chairman John H. Bryan insists that his com-

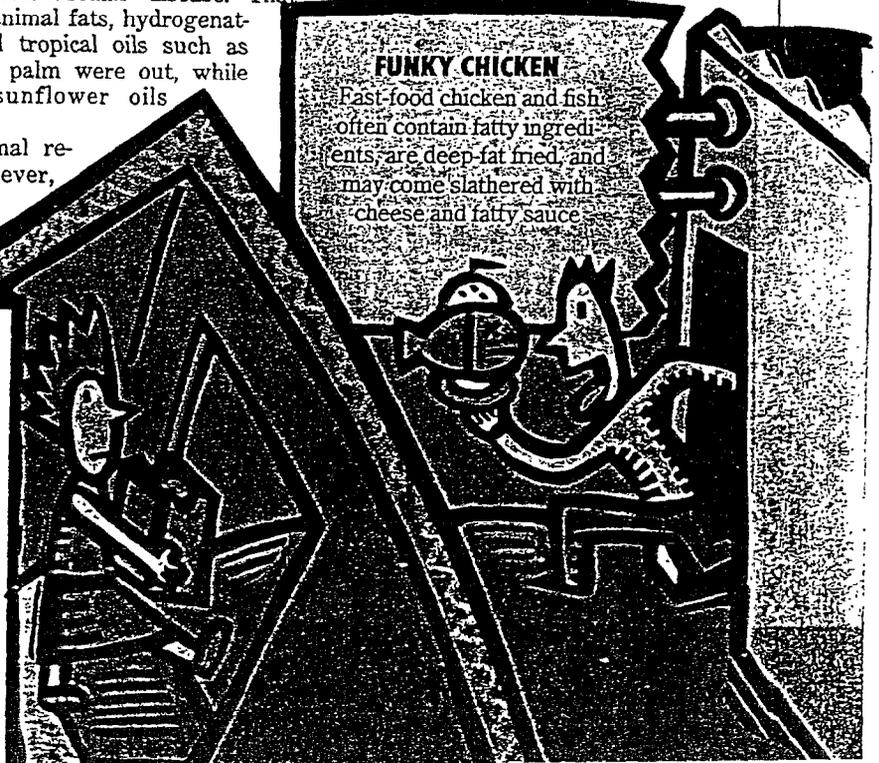
FUNKY CHICKEN

Fast-food chicken and fish often contain fatty ingredients, are deep-fat fried, and may come slathered with cheese and fatty sauce.



THE SCHMEAR FACTOR

Cream cheese has about half the calories of margarine or butter, true. But most people use twice as much



Cover Story

pany wasn't trying to mislead people with its Light Classics desserts, which it renamed to avoid a legal fight with a group of state attorneys general. The "light" referred to the airy texture of the products, not to their caloric content.

In some respects, consumers are better-educated than ever before about nutrition, and they have made long-term changes in their diets (table). In particular, they have been thoroughly convinced of the ills of fat and cholesterol. In 1988, according to the FDA, 59% of Americans said they had had at least one cholesterol test, up from 35% two years earlier. Kraft research shows that two-thirds of consumers claim to be modifying their diets out of concern over fats, cholesterol, and oils.

'SUCH A CHARADE.' But if consumers are worried, they're also perplexed. FDA surveys show tremendous confusion over saturated fat, unsaturated fat, and cholesterol, and where they're likely to be present. And food makers haven't always been helpful. "No cholesterol" labels have sprouted on everything from cookies to bread to cooking oils, though many of these items by definition have none because they are all-vegetable products. Both Best Foods and Kraft introduced no-cholesterol mayonnaises earlier this year, even though regular mayonnaise has little cholesterol to begin with. William R. Baar, vice-president for sales and marketing at Borden's Dairy Div., thinks the food industry is riding health claims, and the cholesterol scare in particular, to ridiculous heights. "This is such a charade, it is unbelievable," he says.

And for all the anticholesterol frenzy, the evidence linking the cholesterol that people eat with the cholesterol in their blood appears to be shaky. Dietary cholesterol "may contribute remarkably little to cholesterol in the blood for most people," says Fergus M. Clydesdale, head of the food science department at the University of Massachusetts. "For the general population, saturated fat is a bigger issue."

If that is the case, some foods without cholesterol may contain a nutritional booby trap. From cookies to crackers and potato chips, many of the products making no-cholesterol pitches contain hydrogenated vegetable oil. Hydrogenation, which hardens oils for use when baking,

also raises their saturated-fat content.

Many foods used to contain the even more highly saturated tropical oils, too, until heart-attack survivor Phil Sokolof, a manufacturer of building materials, horrified food companies late last year by sponsoring a series of full-page ads in major newspapers entitled "The Poisoning of America." The ads pictured such products as Nabisco's

Triscuits, Keebler Club crackers, Kellogg's Cracklin' Oat Bran, Quaker's Granola bars, and Procter & Gamble's Crisco. After a brief fight, most companies reformulated their products using partially hydrogenated oils.

As for the proposition that health messages in food marketing are improving America's diet, the evidence is contradictory. Consumption of beef, which at last count contributed 18% to 20% of the saturated fat that consumers ingest, has been falling since 1976, as has consumption of whole milk. At the same time, people are increasing their consumption of other fatty foods such as cheese and oils. Sara Lee has just turned in a record year of cheesecake sales. And Americans will eat 13 pounds of chips, pretzels, and popcorn each this year, up from 8 pounds in 1979. "One of the things we find about our category is that consumers all talk about wanting healthier foods," says Dwight Risky, vice-president of new products at Frito-Lay Inc. "If they have to make any trade-offs in indulgence, however, they won't buy it."

JADED. The medical marketing of food could well backfire on its practitioners, too. Even if the government doesn't step in with regulations, consumers may revolt. Mona Doyle, president of Consumer Network Inc., a Philadelphia-based marketing research firm that interviews 500 consumers a month, says her studies show "widespread perception of deception in advertising and labeling," especially over the issue of cholesterol and saturated fat. "Consumers felt their ignorance had been traded upon in a very unfair way," she says.

And similar episodes have proven to be fads. Riding a calcium craze a couple of years ago, marketers put extra calcium in everything from sodas to orange juice and milk, but the products haven't fared well.

Despite such doubts, health pitches for food will multiply. Shoppers are becoming more health-conscious, research on diet and health is intensifying, and marketers are adding unusual ingredients for which they can make health claims. General Mills and Kellogg are marketing cereals called Benefit and Heartwise that contain psyllium, a fiber grown in India that is the main ingredient in laxatives such as Metamucil. Some research has shown that the grain may



AMERICANS ARE SMARTER ABOUT DIET AND HEALTH... OR ARE THEY?

	1979	1983	1988
What are causes of high blood pressure?			
Percent who mention fats/cholesterol	25%	46%	35%
Percent who mention dietary sodium	12%	34%	34%
What things that people eat or drink cause heart disease?			
Percent who mention fats/fatty foods	29%	43%	55%
Percent who mention cholesterol	26%	40%	45%
What things that people eat or drink cause cancer?			
Percent who mention fats/fatty foods	12%	19%	25%
Percent who mention food additives	25%	21%	17%

	1983	1986	1988
1. Is cholesterol found in vegetables and vegetable oils, animal products or all foods containing fats?	52%	52%	53%
2. Which kind of fat is higher calorie: saturated fats or polyunsaturated fats, or are they both the same?	35%	37%	40%
3. If a food is labeled cholesterol-free, is it also low in saturated fat, high in saturated fat, or could it be either?	NA	48%	49%
4. Is a product containing vegetable oil low in saturated fat, high in saturated fat, or could it be either?	NA	NA	42%

NA = Not available

DID YOU KNOW THE ANSWERS?

1. Cholesterol is found in animal products. Vegetable oils and vegetable oils can be either high or low in saturated fat. 2. Saturated fats are higher in calories than polyunsaturated fats. 3. A food labeled cholesterol-free can be either high or low in saturated fat. 4. A product containing vegetable oil can be either high or low in saturated fat.

DATA: FDA HEALTH AND DIET SURVEYS

Cover Story

reduce blood cholesterol. And a whole generation of new artificial fats, including NutraSweet Co.'s Simplese and P&G's olestra, is likely to start showing up in America's food before too long.

P&G boasts that olestra alone could cut overall fat consumption to 34% or 35% of total calories from the current 37% just on the basis of the limited uses in products such as potato chips and cooking

oils for which it has sought FDA approval. Kraft General Foods is introducing Sealtest Free nonfat ice cream, using cellulose gel instead of butterfat.

Still more claims will come as marketers find evidence to bolster health pitches for existing products. Even now, there is evidence from animal studies that rice bran may be a cholesterol-lowering agent. That could mean that another

humble staple will soon experience the same apotheosis as the oat. A strange thing can happen when ing and medicine meet.

By Zachary Schiller in C with Russell Mitchell in Minn Wendy Zellner in Battle Creek, La rien in Chicago, Andrea Rothman lecia Konrad in New York, and bu ports

SURE, YOU'RE BUSY. THAT'S NO REASON NOT TO EAT RIGHT

Executives are supposed to be good at planning and follow-through. So establishing a diet and sticking to it ought to be easy for them. That's what dietician Ruth E. Lahmayer thought—until she started giving advice to 60 IBM managers each week as part of a training program in Atlanta. "I had heard that IBMers have got it together," she says. "But not when it comes to eating right. They tell me they don't focus on their diet because they're so focused on their jobs."

Sound familiar? You may be thinking about changing your eating habits and leading a healthier life. But chances are you're a slave to hectic travel schedules, long days at the office, and repeated restaurant and airplane meals. And the task may seem impossible.

But it's not. Joseph L. Aurichio, chief executive officer at Kearney-National Inc., an electrical-equipment maker, changed his diet and began exercising four years ago after finding his cholesterol level was sky-high. He started planning his meals, avoiding certain foods, and insisting on what he wanted at restaurants and on airplanes. "It can be difficult," Aurichio says of his new lifestyle. But he thinks the results are worth it: His cholesterol has declined to 200 from 280.

YUMMY FAT. You don't need to load up on oat bran or any other "magic" food to eat better. Nutritionists generally agree that most people can reduce their risk of heart disease and certain cancers by following simple guidelines: Eat a lot more fruits, vegetables, and whole grains, and eat less salt and fat, particularly saturated fat. While the message is simple, carrying it out is not. Processed and restaurant foods are full of fat—for good reason: Fat makes food taste good.

A nutritionist can help you fit good

food into a busy life and offer tips to keep your taste buds from atrophying. Health clubs and corporate fitness centers often have nutritionists on staff. Some recommendations they're likely to make: In restaurants, order big helpings of vegetables, steamed to preserve the nutrients. Some executives carry packets of special seasonings such as Mrs. Dash to liven up veggies without salt or sauces.

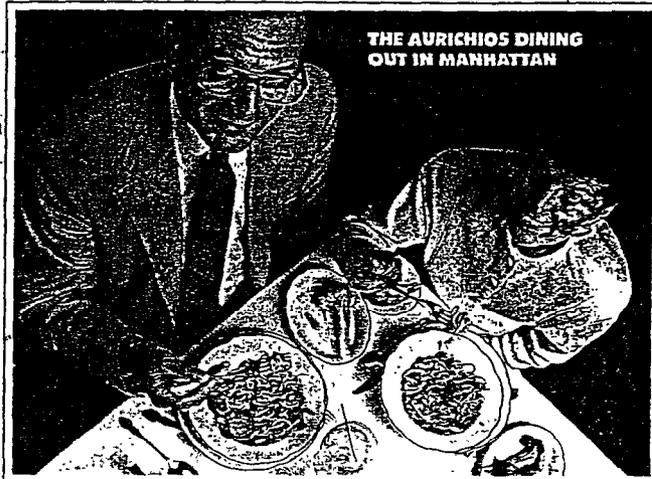
Salads are a great choice, of course, but drowning the greens in fat-laden

57, is on the Pritikin diet, with restricted to 10% of total calories. His wife, Ann, frequents the Foro restaurant in Manhattan, where Joseph Orlandi whips up a whole wheat pasta primavera with oil-free marinara for the occasion. "You can get it done. You just have to speak up for yourself and not be afraid to be different," says Ann.

I'M THE VEGGIE. Leery of making a meal when you're dining out with guests, you're a restaurant regular, the

may be willing to keep a record of your needs. That's why keep discussions with your waiter to a minimum. Some restaurants will also keep a favored customer's no-oil dressing or other special requests in the cooler.

Even airlines are providing healthier meals. Many travel agents will list your preference for a fruit plate or cholesterol dinner on tickets. Computers and book it all with your aisle seat. Introduce yourself as "the vegetarian meal" to the flight attendant so the right meal gets you.



NO-NO FOODS

- Fried meats
- Bacon and eggs
- French fries
- Microwave popcorn
- Mayonnaise
- Corned beef
- Ice cream

YES-YES FOODS

- Grilled or broiled fish
- Oatmeal and fruit
- Baked potato
- Air-popped popcorn
- Mustard
- Turkey breast
- Nonfat frozen yogurt

DATA: BW

dressing defeats their purpose. For a lean but tasty salad, Lahmayer recommends the dip-and-stab method: Order dressing on the side, dip your fork in it, and then stab the greens. "You'll use half or less the usual amount of dressing that way," she says.

Many restaurants will accommodate special needs. But call ahead. Aurichio,

Traveling the rubber-chicken circuit. You may not have a choice of dishes at many conventions and large-meeting lunches and dinners, but you can usually ask the waiter for a fruit or vegetable plate.

If you put in long hours at the desk, even the vending-machine burritos look tempting when hunger pangs at 9 p.m. Instead, buy an electric popper for no-oil, no-salt popcorn at your office.

Healthy eating demands commitment and effort. But it pays off. Most people who trim fat from their diets report a higher energy level. "That's really an incentive now," says Aurichio. "It's so much disease prevention anymore just feel so much better."

By Russell Mitchell in Minneapolis

WHERE DOES THE HEALTH END AND THE HYPE BEGIN?

Making sense of oat-bran mania, the sugar blues, and other dietary disputes

Numerous studies by the National Cancer Institute, the National Research Council, and others support the adage: "You are what you eat." No question, food can play a major role in cancer, heart disease, osteoporosis, hypertension, and other diseases.

But determining whether particular foods—the fiber in All-Bran or the unsaturated fats in rapeseed oil—can actually help prevent a disease such as cancer is no simple matter. Some studies, for example, indicate that people with high-fiber diets have lower cholesterol levels and rates of certain cancers. Saturated fat? Too much can foster heart disease. But too much polyunsaturated fat could make people more susceptible to cancer.

Small wonder that consumers often suffer from their zeal to follow the latest dietary dictums. Reports are on the rise of middle-class children undernourished by low-fat diets. One study found that high-income women who avoided meat, eggs, and milk to cut fat in their diets also reduced beneficial nutrients such as zinc, iron, vitamin B-6, and magnesium. And the women didn't cut their fat intake. They replaced "bad" foods with fat-rich cheese, desserts, and salad dressings.

So what's a person to eat? The best advice is probably the least exciting. Follow those age-old maxims: moderation, variety, and balance. "No single food product, no matter how beneficially formulated or how badly formulated, by itself is going to help or hurt you," says Jeffrey B. Blumberg, associate director of the Agriculture Dept.'s Human Nutrition Research Center on Aging at Tufts University.

Still, it helps to know the virtues—and pitfalls—of various foods. Here's what the latest scientific studies show.

FIBER: CEREAL VS. CANCER

Kellogg Co. started the fiber fad in 1984 when its All-Bran flakes hit the shelves with a label announcing that the cereal might be helpful in preventing some kinds of cancer. The Food & Drug Ad-

ministration was reluctantly forced to go along, in part because the claims were endorsed by the National Cancer Institute. Since then, food products boasting fiber from oat bran to psyllium have proliferated.

But the fiber-cancer connection is still based mainly on studies of diets in other countries. The results of animal studies and other laboratory experiments in the U. S. have been inconclusive. Fiber, however, does seem to reduce intestinal polyps, a precursor to colon cancer. A four-year study at New York's Cornell Medical Center and Memorial Sloan-Kettering Cancer Center found that polyps shrank in some test subjects who ate two bowls of Kellogg's All-Bran daily.

The role of fiber in heart disease is also murky. In one study, men who ate 1 1/4 cups of oat bran each day did indeed bring their cholesterol levels down as much as 14%. But how does oat bran do it? Scientists know the liver uses cholesterol to make bile acids. The soluble fiber found in oat bran may attach to bile acids, causing them to be excreted from

the body. When that happens, the liver takes more cholesterol out of the bloodstream to replace the bile acids. One problem: Soluble fiber found in beans, which also can reduce cholesterol in the bloodstream, does not bind bile acids.

But that's not to say fiber is a waste. Dr. Victor Herbert, a professor at Mount Sinai School of Medicine in New York, wary of the cancer and heart findings, still advises American to consume 20 to 30 milligrams of fiber a day. "It's good for regularity," he says.

SALT AND SUGAR: CUT DOWN ON CUTTING DOWN

When concerns over the health effects of diet began to surface more than 20 years ago, salt and sugar were demons. But these days, they are less important.

The National Research Council still maintains that a long-term high-salt intake is strongly linked to high blood pressure. Recent research, however, is proving that this may be simplistic. "Accusing sodium intake of causing hy-



pertension is an overgeneralization," says John W. Erdman, a University of Illinois professor of food science.

For one thing, sodium is not the only mineral that affects blood pressure. Deficiencies of calcium and magnesium also contribute. And of the 15% to 17% of Americans genetically prone to hypertension, only half are sensitive to salt. Since they can't yet be identified, the advice to everyone, especially blacks (who have an unusually high rate of hypertension) and people who have a history of hypertension in their families, remains: Limit your salt intake and keep minerals in balance.

Sugar is a big source of calories and a cause of cavities, but otherwise don't worry about it. But do artificial sweeteners help curb obesity? "They are not a magic bullet," says Fergus M. Clydesdale, of the University of Massachusetts' food science school. Indeed, studies indicate that many people who use artificial sweeteners actually consume more sugar—the Sweet 'N Low-in-the-coffee, chocolate-cake-for-dessert syndrome.

CALCIUM: A BONE-BUILDER —AND MUCH MORE

For a decade, studies have indicated that the embrittlement of bones in the elderly—osteoporosis—might be linked to a lack of calcium in the diet. What may prove to be the definitive study was released last November. Scientists at the University of Southern California tracked a group of 65-year-olds for 15 years, dividing them into three groups, according to calcium intake. At the end of the study, those who ranked in the

highest third for calcium consumption had 60% fewer hip fractures than those in the lowest third of the group. These effects can be reduced by eating too much protein. In 1987, researchers found a link between high-protein diets and osteoporosis. Another study shows that if protein intake is doubled, 50% more calcium is lost in urine. The National Center for Health Statistics says children eat twice as much as the recommended levels of protein, the average middle-aged man eats 60% more than recommended, and the average middle-age woman 25% more, so many Americans could be calcium-deficient.

But preliminary research now indicates that calcium may also help protect against colon cancer. According to Dr. Martin Lipkin, a gastroenterologist at Memorial Sloan-Kettering, calcium has reduced drug-induced colon cancer in rats. And in the test tube, calcium can decrease the cancer-like rapid growth of colon cells. Moreover, studies of populations with high-calcium diets—Finland and Denmark, for example—show that they have fewer colon cancers. Now, studies are under way in which people at risk for colon cancer are given 1,200-to-2,000-milligram supplements of calcium.

FATS: THE IDEAL POINT OF SATURATION

Most of us eat a diet that is about 37% fat, 13% of it made up of saturated oils. The experts, however, recommend that your diet contain no more than 30% fat, with saturated fat just 10% of that total.

For good reason. There is a link between saturated fats and obesity. And

saturated fats contribute to high blood cholesterol—a risk factor for heart disease, even though the effect of lowering cholesterol levels on longevity is a subject of scientific dispute (page 128). "The amount of cholesterol produced by the body and the rate it is removed from the bloodstream is controlled in part by saturated fat," says Mark A. Kantor, a food and nutrition specialist at the University of Maryland. Saturated fat raises the level of low-density lipoproteins (LDLs), the substances in the blood that carry cholesterol and seem to be involved in building deposits in arteries.

Dr. Ernst J. Schaefer, chief of the lipid metabolism laboratory at Tufts University's Human Nutrition Research Center on Aging, says reducing saturated fat consumption by 50% may lower blood cholesterol twice as much as a similar drop in dietary cholesterol.

As an alternative to saturated fats, vegetable-based polyunsaturates can reduce total cholesterol levels in some people. But there may be a trade-off: High levels of polyunsaturated fats may be culprits in breast and colon cancer. A fatty acid called Omega 6, found in vegetable oils, seems to promote tumors, according to Nitin Telang, a biochemist at Memorial Sloan-Kettering. In contrast, studies show that a diet rich in the fatty acid Omega 3—found in fish and soybean oil—seems to retard tumor growth.

Even better are monounsaturated fats found in olive and rapeseed oil. They reduce LDL levels without lowering levels of "good" cholesterol, called HDL, for high-density lipoprotein, that removes arterial plaque. Nor have these oils yet been implicated in cancer. In Greece and Italy, where lots of olive oil is consumed, heart disease and cancer rates are low.

NUTRITION IN THE FUTURE: FOODS THAT FIGHT AGING

It's still very controversial, but some scientists think diet can help stave off the effects of aging. One who does is Tufts University's Blumberg, who is studying the effects of a group of substances that are antioxidants: vitamin C, beta carotene, and vitamin E.

Antioxidants sop up rogue oxygen atoms, called free radicals, that some researchers believe roam through the bloodstream, wreaking havoc on cells and organs and increasing aging effects and the risk of cancer. Referring to a study soon to be published in the *New England Journal of Medicine*, Blumberg says that "dietary supplements of antioxidants are associated with a reduced risk of cataracts. We also found that supplements of vitamin E can substantially boost the immune system."

But not all scientists hold these views. A massive diet study from the National



Cover Story

Research Council recommends against such dietary supplements. And Dr. Wayne R. Bidlack of USC says: "I think some of the claims being made about beta carotene are bordering on fraudulent. A normal diet with the recommended levels of vitamins E, C, and beta carotene will protect against free radicals."

Blumberg acknowledges the criticism but says: "You don't need supplements

if you comply with their guidelines to eat six half-cup portions of vegetables a day and three fish meals a week. But many people don't eat appropriately or can't absorb enough nutrients."

Will "antiaging" foods become the next dietary fad? "I know it's going to happen, because we have food company reps passing through our labs all the time," says Blumberg. He suggests

these products will probably be in the form of high-nutrient foods for older people who don't eat much. With nearly 20% of the population projected to be older than 65 in 2000, this could be another lucrative tool for food marketers.

By Naomi Freundlich in New York, with Wanda Cantrell in Chicago, Laura Jereski in Boston, and Peter Hong in Washington

Cover Story continues on page 133.

BLOOD PRESSURE IS RISING IN THE CHOLESTEROL DEBATE

These days, guests at cocktail parties are as likely to exchange lipid levels as tennis scores. Reacting to a barrage of publicity by the federal government, millions have rushed to their doctors for a cholesterol count. To cut cholesterol—and, they hope, the risk of fatal heart disease—Americans have replaced bacon and eggs with oat bran muffins, shunned red meat, and sworn off rich desserts.

But some medical experts are challenging the theory that cutting down cholesterol is the key to a longer life. The debate, which has been simmering in the medical community for several years, was thrust into the public eye by an article in the September issue of *The Atlantic* that attacked the scientific basis for reducing cholesterol.

Most of the dissenters agree that cholesterol is a factor in forming the fatty deposits that cause heart disease. Nor do they dispute that the right diet can lower blood cholesterol by as much as 10%. But, they argue, just how important an overall role it plays is still to be determined. High blood pressure, smoking, obesity, and the influence of genes, age, and sex are also important. "Cholesterol is being looked at as the sole risk factor, but it's not," says Robert E. Olson, professor of medicine and pharmacology at the State University of New York at Stony Brook.

DANGER ZONE. The National Heart, Lung & Blood Institute (NHLBI) set off the national obsession with cholesterol in 1985 when it launched the National Cholesterol Education Program. Its message: People with high levels of cholesterol in their blood—240 milligrams per deciliter or 200 milligrams if combined with other risk factors such as smoking or high blood pressure—have a higher risk of heart disease. That put one-third of the adult population in the danger zone.

From the start, the effort was controversial. "We had to vote on the program five times before it passed," recalls Dr. Eliot Corday, a clinical

professor of medicine at the University of California at Los Angeles School of Medicine. But early this year, the National Research Council went further. It reported that a 10% drop in serum cholesterol levels can cut the risk of heart disease by 20%. To get there, it said, cut back on saturated fats and cholesterol and eat more fiber.

Although the scientific research behind that advice includes hundreds of

later to examine the link with diet, he says, the results were inconclusive.

The second study, completed in 1984 and sponsored by NHLBI, followed for seven years nearly 4,000 middle-aged men who had serum cholesterol levels averaging 290. The objective: measure how a cholesterol-reducing drug affected the heart-attack rate. The study showed a 20% drop in heart attacks for men taking the drug. But those who took the drug had the same mortality rate as those who took a placebo.

EATING SCARED. Another more recently completed study, this one designed to see if those with above-average cholesterol levels benefit from a change in diet, came to a similar conclusion. The Multiple Risk Factor Intervention Trial, begun in 1982, looked at 12,866 high-risk men. "After seven years, we saw no difference in the mortality rate in people who followed a cholesterol-lowering diet," says UCLA's Corday.

To Olson and others, the government's call for changing the habits of 60 million adults—without clear evidence that it will help—is tantamount to scare tactics. "This program has made people with what I consider low serum cholesterol afraid of what they eat," says Olson. What's more, studies show that half the people with high blood cholesterol do not respond to dietary changes, anyway, because genetics play the dominant role. But under the NHLBI guidelines, millions might be treated with costly drugs.

The NHLBI, however, defends its position. "The public wants advice about reducing the risk of heart disease now," counters Mark A. Kantor, a nutritionist at the University of Maryland. But NHLBI is also trying to get some better data. It intends to start a new clinical test to determine if women and the elderly can benefit from lowered cholesterol. This is welcome news to scientists who think it makes more sense to find out who can really be helped before writing a prescription.

By Naomi Freundlich in New York



SUNY PROFESSOR OLSON: THE GOVERNMENT IS GUILTY OF SCARE TACTICS

published studies, two were pivotal in setting current recommendations. And neither is conclusive. The first, an ongoing study called the Framingham Heart Study, has followed the diet and serum cholesterol levels of an entire Massachusetts town for over 30 years. The results show a link between high blood cholesterol levels and a higher rate of heart attacks, says Peter Wilson, director of laboratories for the study. But when scientists went back

RULE 1 FOR G-7: DON'T INTERVENE

The Group of Seven industrial nations is playing its familiar game. On the eve of the annual International Monetary Fund meeting, the G-7 issued a communiqué decrying the dollar's recent strength as "inconsistent with longer-run economic fundamentals." Central banks then followed up by dumping dollars into currency markets, knocking down the greenback by 5 pfennigs and 4 yen. Finance ministers congratulated each other—but soon the dollar was creeping back up as the effects of intervention wore off.

After four years of currency manipulations, the G-7 still prefers to ignore the most basic rule of the markets: Intervention, no matter how massive, can't keep the dollar down when interest rates and growth rates here and abroad are driving it up. The Federal Reserve's anti-inflation campaign is keeping U. S. interest rates high. Japan and West Germany, while complaining about the dollar's strength, haven't been willing to hike their rates and risk slower growth.

The G-7 is right, of course, about the longer-run effects of a strong dollar: Global trade imbalances will tend to worsen, since the dollar's current level won't help U. S. exporters and will only assist German and Japanese exporters. But if the finance ministers really want to do something to push the dollar down, they need to do some spadework at home. The U. S. should engage in some serious budget-cutting, while the Japanese should let more imports wend their way through the country's clogged distribution channels. The Germans could nudge their interest rates higher, while U. S. policymakers could nudge theirs lower—if they conclude that the dangers of persistent trade deficits outweigh the risk of inflation. By pretending that intervention alone can right the imbalances, the G-7 only undercuts its credibility on serious matters of policy coordination.

PITTSTON SHOULD STAND BY ITS PROMISES

Stung by the soaring cost of providing medical benefits to employees, many companies are shifting more of the burden to their workers. Although such steps are often unavoidable, they are most distressing when promises to retired workers are abrogated—particularly when those promises were made in exchange for concessions by the very people whose benefits are threatened.

That, in fact, is the root cause of the extraordinarily bitter strike now being waged by the United Mine Workers against Pittston Co. in Virginia, West Virginia, and Kentucky. Back in 1950, the UMW, led by John L. Lewis, negotiated a milestone labor pact with major coal companies, including Pittston. The industry agreed to make royalty payments on each ton of coal produced to provide pensions and lifelong medical benefits for all miners with 20 years of service. In return, Lewis encouraged the operators to mech-

anize, confident that the new funds would give old-age protection to the thousands who lost their pick-and-shovel jobs

The upshot was a period of labor stability during which coal operators, with the UMW's blessing, achieved enormous productivity gains by adopting labor-saving machinery and eliminating some 300,000 jobs in Appalachia. Now, however, Pittston, citing competitive pressures in world coal markets, refuses to make contributions to a health care fund covering some 118,000 pre-1974 pensioners and their spouses and widows—a shrinking group whose average age is 76. Other coal operators are still contributing but indicate they will also withdraw from the funds if Pittston gets its way. If that happens, active UMW members will undoubtedly launch a protracted, industrywide work stoppage.

The UMW itself has undermined the financial condition of the fund by engaging in wildcat strikes in recent years. But that doesn't absolve Pittston—which does not claim to be in financial straits—from its moral obligation. If it needs to cut labor costs, it should make its case forthrightly. And rather than turn its back on retirees, it should seek to secure efficient work practices and other cost savings from labor.

FOR BETTER NUTRITION, TRY BETTER LABELS

It's a symptom of the information age: More and more tidbits are released daily about the effect of diet on health, and more and more consumers find themselves puzzled about just what to do. Even the scientists can't agree. Enter the food marketers, eager to cater to the public's newfound obsession with nutrition—in some cases by eliminating such harmful ingredients as palm and coconut oils from their products, but more often by adorning their packages and advertising with exaggerated, confusing, or misleading health claims (page 114).

More than anything, the American public needs to have information delivered clearly, concisely, and accurately. Today, most packaged foods regulated by the Food & Drug Administration (everything but meat, poultry, eggs, and booze) must simply list their ingredients by order of predominance. Only manufacturers making nutritional claims must provide nutrition tables, and these are hopelessly out of date, with no requirement that amounts of cholesterol, saturated fats, or dietary fiber be disclosed. Meanwhile, marketers have been making increasingly dubious health claims ever since the FDA failed to challenge a 1984 Kellogg Co. claim that the fiber in All-Bran lowered the risk of cancer.

We favor a bill before Congress sponsored by Representative Henry A. Waxman (D-Calif.) that would mandate complete nutritional information on all food packages in a readily comprehensible, user-friendly format. We also agree that guidelines for the use of "high" and "low" when applied to nutritional components such as fiber or cholesterol are desirable. But the bill's intention to set rules for health claims by food manufacturers would create a bureaucratic thicket. Better to reinstate the traditional ban on explicit health claims and concentrate on providing nutritionally aware consumers with the accurate product information they require.

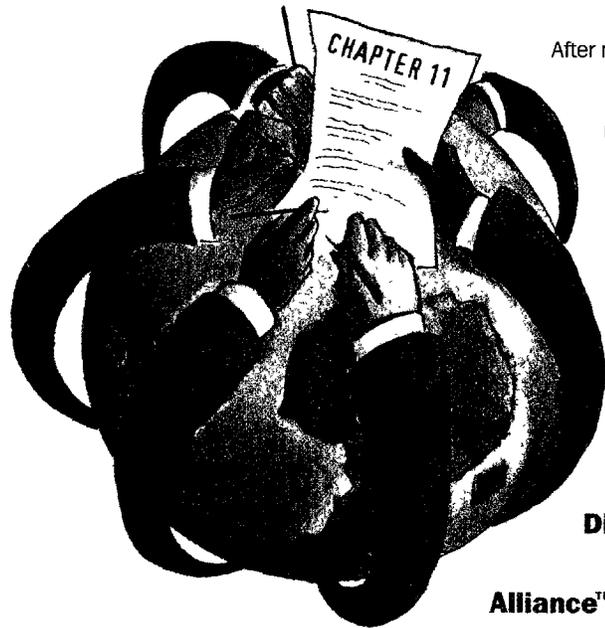
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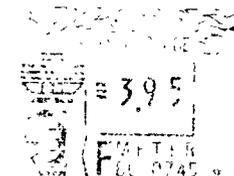
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