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FDA Should Allow Food Labeling Claims About Nutrient Content And Health

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Executive Summary

Recent court cases finding that the Food and Drug Administration's bans on certain health claims are unconstitutional have prompted the agency to solicit comments about new approaches to food labeling. We recommend that FDA allow all nutrient content claims and all health claims, unless it can show them to be false and misleading. In particular, FDA should approve in advance any statements that quote or paraphrase authoritative peer-reviewed scientific studies. These changes are likely to substantially improve a consumer's ability to choose food based on information about its nutritional content and its likely effects on health.

FDA Should Allow Food Labeling Claims About Nutrient Content And Health

Randall Lutter and Elisabeth Irwin

Recent court decisions striking down the Food and Drug Administration's restrictions on constitutionally protected commercial speech have forced the FDA to reconsider its food labeling regulations. The way that FDA solicits comments about how to revise its programs to conform to these decisions demonstrates their profound implications. FDA asks,

“Do FDA’s speech related regulations advance the public health concerns they are designed to address?”¹ “Are there any regulations, guidance, policies and practices FDA should change, in light of governing First Amendment authority?”²

The recent *Pearson v. Thompson* decision by U.S. District Court for the District of Columbia implies that FDA may not constitutionally prohibit a health claim merely because the FDA believes the supporting scientific literature is inconclusive.³ This decision complements the Supreme Court ruling in *Thompson vs. Western Medical Center*:⁴ even when a restriction on commercial speech directly advances an important government interest, the government can and should advance its interest by adopting restrictions less burdensome than a ban. Together, these decisions require that FDA make a sharp departure from its current food labeling policy.

In light of these decisions, we make two general recommendations to the FDA about how to reform food labeling regulations so as to better provide consumers the nutritional information they need to purchase health-promoting foods: (1) To promote the dissemination of information about nutrients newly found to be important, we recommend that FDA allow all nutrient content claims that cannot be shown to be false or misleading. (2) In addition, we recommend that FDA allow any diet-disease claim about the health benefits of a particular food if the claim relies upon a reasonable basis, such as peer reviewed scientific research, and there exists no evidence that it is false or misleading.

¹ See FDA (2002, p. 34944).

² See FDA (2002, p. 34944).

³ See U.S. District Court of the District of Columbia (2001).

⁴ See U.S. Supreme Court (2002).

We elaborate on the advantages of these recommendations below. To support our views we consider how FDA regulates labeling of two types of fat linked to heart disease: a “good” fat (omega three (n-3) polyunsaturated fatty acids) and a “bad” fat (*trans* fatty acids).

Our recommendations follow from a key empirical fact. Increased consumer awareness of key diet-health links, increased production of foods that promote health, and increased consumption of such foods, all followed the relaxation of food labeling regulations in the mid-1980s.⁵ Several observations on the value of useful information about nutrient content and the incentives to supply it, also support these recommendations.

First, more information about nutritional content and links between nutrition and health would benefit consumers. Chronic disease, especially coronary heart disease (CHD), is a major cause of death for Americans; some estimates suggest that a significant portion of deaths from chronic disease could be averted through better nutrition.⁶ Information about the nutritional content of specific foods as well as nutrition-disease links is essential if these health gains are to be realized. Moreover, nutrition information must be understood not only in the abstract by government officials and scientists, but by individual shoppers who choose foods with limited time and money.

Second, information about nutrition-disease links is dynamic—a result of constant changes in scientific understanding—so a satisfactory regulatory process must deliver new information quickly. The fundamental policy challenge is thus to encourage food suppliers to better inform consumers about the nutritional properties of foods and diet-disease links. We elaborate below on how FDA’s current regulatory program has failed to keep consumers informed about new research on the nutritional effects of different forms of fat.

Third, given the dynamic nature of information about nutrition-disease links, the supply of information is likely to respond to incentives. The quality and quantity of new research about the effects of diet on health may increase as the value and importance of such information increases. While nutritional information is intrinsically not patentable, and therefore unlikely to develop the proprietary aspects of information about new pharmaceutical products, we believe the importance of

⁵ See FTC (1996).

⁶ See, e.g., McGinness and Foege (1993), and Hu (2002).

incentives in directing new nutrition research has not been adequately appreciated. Labeling regulations that facilitate nutrient content and health claims are likely to spur additional research into such effects, and such research may itself have significant social benefits.

Fourth, research indicates that consumers distinguish the quality of information by the credibility of its source.⁷ There may be substantial advantages to greater competition in food quality as described on labels, as consumers are likely to treat manufacturers' simple assertions more skeptically than conclusions of scientific researchers in peer-reviewed journals or endorsements by third parties committed to better foods.

Perhaps the most compelling rationale to reform FDA food regulation is that it has badly served consumers' right to know what they are eating. If reputable scientific journals publish studies finding links between particular nutrients and disease, government has a deep and fundamental responsibility to allow retailers and manufacturers to list this information, and not to suppress it for years.

FDA currently prohibits many nutrient content claims (sometimes called descriptors) and health claims. In addition FDA prohibits factually correct content claims about nutrients not listed on its Nutrition Facts panel. For example, manufacturers cannot state on food labels that foods are free from or low in *trans* fat, or high in n-3 polyunsaturated fatty acids, because FDA has not defined these terms.⁸ In addition, FDA bans any health claim unless it finds in advance that it is supported by "significant scientific agreement."⁹ We believe that FDA's restrictive regulation of health claims and nutrient descriptors should be substantially relaxed in light of the new Court decisions.

Recommendation 1: The FDA should accept all nutrient content claims not found to be false or misleading using an evidence-based rule of reason.

FDA currently allows relative nutrient content claims only for nutrients for which daily values exist.¹⁰ For example, it prohibits "low in trans fatty acids," or "higher in omega 3 fatty acids than

⁷ Calfee and Ringold (1994).

⁸ See FDA (1994, Chapter 6, Question 21).

⁹ See 21 U.S.C. 343(r)(3), and FDA (2001).

¹⁰ See FDA/CFSAN (2001).

brand x.”¹¹ These restrictions are problematic because daily values for *trans* fatty acids and n-3 fatty acids do not now exist, even though the peer-reviewed scientific literature shows a large and growing consensus supporting adverse health effects of *trans* fats and beneficial effects of n-3 fatty acids.¹² Indeed, regarding *trans* fats, the National Research Council recently concluded “any incremental increase in intake increases CHD risk.”¹³ It refrained, however, from issuing a daily value.¹⁴

While FDA does allow food manufacturers to make statements regarding the absolute levels of nutrients not listed on the Nutrition Facts Panel, such as *trans* and omega 3 fatty acids,¹⁵ disclosure of relative levels is key because it may help justify the cost of a voluntary labeling change or marketing campaign based on the diet-disease links.

FDA’s current approach keeps consumers in the dark. Consumers have not learned about the health effects of *trans* fatty acids in their food,¹⁶ even though concerns about *trans* fatty acids have been in the scientific literature for nearly 10 years.¹⁷ Food labels do not indicate n-3 levels, though the literature has suggested health benefits.¹⁸ Moreover, delays in customer awareness will persist because the National Research Council in its most recent report has not established daily values for either *trans* fats or for n-3 fatty acids,¹⁹ and FDA may take years to issue a final rule after NRC issues daily values.

The premise of the current approach, that disclosing relative nutrient levels is impossible without official daily nutrient values, is fundamentally flawed. It postpones references to diet-disease links on food labels until many years after credible evidence of diet-disease links first appears in authoritative scientific journals.

We recommend that FDA identify immediately a collection of truthful and non-misleading relative nutrient content claims that would be safe from FDA enforcement action. For example, FDA should approve in advance any comparative claim that brand x of food category x is lower in *trans*

¹¹ See FDA (1994, Chapter 6, Question 22).

¹² For a summary, see NRC (2002).

¹³ NRC (2002, p. 8-66).

¹⁴ See NRC (2002).

¹⁵ See FDA/CFSAN (1994, Question 22).

¹⁶ See Guthrie et al. (1999).

¹⁷ See Willett et al. (1993).

¹⁸ See, e.g., Hirai et al. (1980).

fatty acids than brand y or food category y, provided that the levels of *trans* fatty acids in the two brands or categories are identified. Similarly, claims that food A is higher in n-3 than food B should also be allowed, provided that the levels in the two foods are specified. Such simple policy changes would sidestep the delay of defining terms and convey substantial new and valid information about the nutritional content of foods to consumers.

Recommendation 2: Health claims should be permitted unless found to be false or misleading using an evidence-based rule of reason.

The FDA currently imposes a very stringent standard for health claims, requiring, in accordance with the Federal Food Drug and Cosmetic Act, that they be supported by “significant scientific agreement.”²⁰ Many potential—and still banned—health claims are supported by scientific evidence that is persuasive, but not yet, in FDA’s judgement, supported by significant scientific agreement. “Significant scientific agreement” tends to require directed reports by the NRC as well as a lengthy rulemaking process specific to each nutrient. As analysts have known for years, policies on health claims that inadvertently prohibit genuinely true claims can misinform consumers about the health consequences of their decisions and have adverse effects on public health.²¹ By relaxing its current, restrictive approach, FDA is likely to significantly improve consumers’ knowledge of foods likely to affect risks of chronic disease.

To clarify permissible health claims, the FDA should specify claims that are “safe harbors.” In particular, the FDA should allow labels to reproduce any and all statements by the National Research Council that connect diet to risk of chronic illness. Furthermore, the FDA should allow direct quotes from all articles published in peer-reviewed journals, provided that such quotes are in context. Finally, the FDA should encourage parties independent of food manufacturers, such as the American Heart Association, to offer stamps of approval to foods that it believes promote healthy hearts.

¹⁹ See NRC (2002).

²⁰ See 21 U.S.C. 343(r)(3).

²¹ Calfee and Pappalardo (1991).

This recommendation will result in a much more expansive set of health claims than is now permitted and will better inform consumers about the consequences of their food purchasing decisions. First, competition among food manufacturers will induce them to make distinctions among different types of health claims. Consumers will give the greatest weight to claims by the National Research Council, endorsements by the American Heart Association, or the FDA. Claims that appear in the academic literature without endorsement by expert panels will receive less attention. Claims made on the basis of poorly designed studies that have not passed peer review will be relatively unattractive to manufacturers because they are easily discredited and have little more credibility than simple assertions.

Moreover, relaxing the restrictions on health claims will greatly increase consumer information. A recent survey of consumer knowledge about the relationship between nutrition and health found a greater ignorance about *trans* fatty acids, for which FDA bans all health (and comparative nutrient content) claims, than saturated fats, for which FDA has allowed limited health and nutrient content claims.²² This suggests that consumer information increases when restrictions on labeling are reduced.

This policy will encourage more truthful and non-misleading claims. For example, FDA's "model" claim for saturated fats is "While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease."²³ FDA requires the statement to refer to both saturated fat and cholesterol, even though the NRC concludes simply "any incremental increase in [saturated fat] intake increases CHD risk."²⁴ It is striking that FDA policy to date has essentially banned such quotes from food labels, even though their greatest value lies with consumers who need to make more informed choices to significantly reduce their CHD risk.

The FDA also bans health claims about *trans* fatty acids, although it has been trying to reform this policy.²⁵ The NRC reports that *trans* fats are not essential and provide no known benefit

²² See Guthrie et al. (1999).

²³ FDA/CFSAN (1994, Appendix C).

²⁴ See NRC(2002, p. 8-50). The NRC goes on to add 'It is neither possible nor advisable to achieve 0 percent of energy from saturated fatty acids in typical whole food diets,' because 'all oils and fats are mixtures of fatty acids.'

²⁵ See Tommy Thompson (2002).

to human health.²⁶ It also states that any increase in *trans* fatty acid intake increases CHD risk.²⁷ Further, NRC recommends that intake of *trans* fatty acids be as low as possible while consuming a nutritionally adequate diet.²⁸ Ironically, FDA's policy on health claims involving *trans* fatty acids is more restrictive than its policy involving saturated fats, even though the NRC review suggests that *trans* fatty acids are more effective at raising cholesterol levels than saturated fats.²⁹ These NRC conclusions and similar statements should be promptly made available to American shoppers by allowing them to be included on food labels.

In the case of n-3 fatty acids from fish, health claims that successfully affect consumer behavior could provide substantial improvements in health, according to a growing body of scientific research. Hu et al. report that the relative risk of fatal CHD among women without previous diagnoses of CHD or cancer falls by nearly half as n-3 intake rises.³⁰ Marchioli et al. of the GISSI-Prevenzione Investigators, in a study of survivors of myocardial infarction, found that a randomly assigned n-3 dose of one gram per day reduced the risk of sudden death from CHD by half within 4 to 8 months.³¹ Albert et al. found that n-3 fatty acids in fish are strongly associated with a reduced risk of sudden death among men without prior evidence of cardio-vascular disease, based on an analysis of healthy men over 17 years.³² These studies confirm earlier research³³ that n-3 intake lowers the risk of CHD for men and women of varying health.

Intake of n-3 fatty acids also appears to protect against a variety of health conditions unrelated to heart disease. These include inflammatory diseases such as rheumatoid arthritis and asthma,³⁴ epileptic seizure,³⁵ endometrial cancer,³⁶ age-related macular degeneration,³⁷ prostate cancer,³⁸ and premature birth.³⁹

²⁶ See NRC (2002, p. 8-2).

²⁷ See NRC (2002, p. 8-2).

²⁸ See NRC (2002, p. 8-2).

²⁹ See NRC (Figure 8-4).

³⁰ See Hu et al. (2002).

³¹ See GISSI-Prevenzione Investigators (2002).

³² See Albert et al. (2002).

³³ Marckmann, et al reported that optimum fish intake of 40 to 60 grams per day would lead to approximately a 50 percent drop in death from CHD. (1999). See also Albert et al. (1998), Burr et al. (1999), Daviglus et al. (1997), and Zhang et al. (1999).

³⁴ See Calder et al. (2002).

³⁵ See Schlanger et al. (2002).

Irrespective of one's views about the health effects of increased n-3 intake, allowing voluntary disclosure of n-3 contents would provide consumers who believe that such benefits may exist—a entirely plausible position given the existing studies—an opportunity to choose their diet accordingly.

In conclusion, FDA's efforts to reform its regulations to allow constitutionally protected commercial speech could substantially improve the public's knowledge of both the nutrients in foods and the links between diet and health, provided that the agency permits a broad range of claims on labels that are truthful and not misleading.

³⁶ See Terry et al. (2002).

³⁷ See Seddon et al (2001).

³⁸ See Terry et al. (2001).

³⁹ See Allen et al. (2001).

References

- Albert, Christine M., Hannia Campos, Meir J. Stampfer, Paul M. Ridker, JoAnn E. Manson, Walter C. Willett, and Jing Ma. 2002. "Blood levels of long-chain n-3 fatty acids and the risk of sudden death." *New England Journal of Medicine* 346:1113-1118.
- Albert, C., C. Hennekens, C. O'Donnell, U. Ajani, V. Carey, W. Willett, J. Ruskin, J. Manson. 1998. "Fish Consumption and Risk of Sudden Cardiac Death." *Journal of the American Medical Association*. Vol. 279. No. 1. January 7, 1998, 23-28.
- Allen KG, Harris MA. 2001. "The Role of n-3 Fatty Acids in Gestation and Parturition." *Experimental Biology and Medicine* (Maywood) 226(6):498-506.
- Burr, M. A. Fehily, J. Gilbert, et al. 1999. "Effects of Changes in Fat, Fish and Fibre Intakes on Death and Myocardial Reinfarction: Diet and Reinfarction Trial (DART)". *The Lancet*. 2: 757-761.
- Calder PC, Yaqoob P, Thies F, Wallace FA, Miles EA. 2002. "Fatty Acids and Lymphocyte Functions." *British Journal of Nutrition* 87: Supplement 1:S31-48.
- Calfee, John E., and Janis Pappalardo. 1991. "Public Policy Issues in Health Claims for Foods." *Journal of Public Policy & Marketing* 10(1): 33-53.
- Calfee, John E. and Debra Jones Ringold (1994) "The Seventy Percent Majority: Enduring Consumer Beliefs About Advertising," *Journal of Public Policy and Marketing*, Vol. 13, no. 2 (Fall), p. 228-238
- Clinton, William. 1993. Executive Order 12866: Regulatory Planning and Review. Washington, D.C.: Public Papers of the Presidents. Available at <http://www.sba.gov/ADVO/laws/eo12866.html>.
- Daviglus, M. J. Stamler, A. Orenca, A. Dyer, K Liu, P. Greenland, M. Walsh, D. Morris, R. Shekelle. 1997. "Fish Consumption and the 30 Year Risk of Fatal Myocardial Infarction." *New England Journal of Medicine*. Vol. 336:1046-1053.
- Federal Trade Commission. 1996. *Information and Advertising Policy: A Study of Fat and Cholesterol Consumption in the United States, 1977-1990*. Available at <http://www.ftc.gov/be/fatexsum.htm>.
- Food and Drug Administration. 2002. "Request for Comment on First Amendment Issues". *Federal Register*, Vol. 67, No. 95. p. 34943. Thursday, May 16, 2002. p. 34943

- Food and Drug Administration. 1999. "Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims; Proposed Rule." Federal Register 64, November 17, 1999, pg. 62745.
- Food and Drug Administration. 1993. "Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label." Federal Register 58, January 6, 1993, p. 2079.
- Food and Drug Administration and Center for Food Safety and Nutrition. 2001. "Claims That Can Be Made for Conventional Foods and Dietary Supplements." Available at <http://www.cfsan.fda.gov/~dms/hclaims.html>.
- Food and Drug Administration and Center for Food Safety and Nutrition. 1999. "Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements." Available at <http://www.cfsan.fda.gov/~dms/ssaguide.html>.
- Food and Drug Administration and Center for Food Safety and Nutrition. 1994. A Food Labeling Guide. Available at <http://vm.cfsan.fda.gov/~dms/flg-toc.html>.
- GISSI-Prevenzione Investigators. 2002. "Early Protection Against Sudden Death by n-3 Polyunsaturated Fatty Acids After Myocardial Infarction: Time-Course Analysis of the Results of the Gruppo Italiano per lo Studio della Sopravvivenza nell'Infarto Miocardio (GISSI)-Prevenzione." *Circulation* 105(16): 1897-903.
- Guthrie, J.F., B.M. Derby, and A.S. Levy. 1999. What people know and do not know about nutrition, In Frazao, E. (Ed.), *America's Eating Habits: Changes and Consequences*. U. S. Department of Agriculture, Economic Research Service, Food and Rural Economics Division. Agriculture Information Bulletin No. 750, pp. 243-280, April 1999.
- Hirai, A. et al. 1980. "Eicosapentaenoic Acid and Platelet Function in Japanese." *Lancet* 2: p. 1132-1133.
- Hu, Frank, Leslie Bronner, Walter Willett, Meir Stampfer, Kathryn Rexrode, Christine Albert, David Hunter, Joann Manson, "Fish and Omega-3 Fatty Acid Intake and Risk of Coronary Heart Disease in Women", *Journal of the American Medical Association*, April 10, 2002, Vol. 287, No. 14, 1815-1821.
- Marckmann P., M. Gronbaek. 1999. "Fish Consumption and Coronary Heart Disease Mortality". *European Journal of Clinical Nutrition*. Vol 53, 585-590.

- McGinnis J. Michael and William H. Foege. 1993. "Actual Causes of Death in the United States." *Journal of the American Medical Association* 270 (18): 2207-12.
- National Research Council, Food and Nutrition Board. 2002. Dietary Reference Intakes for Energy, Carbohydrates, Fiber, Fat, Protein and Amino Acids (Macronutrients): A Report of the Panel on Micronutrients, Subcommittees on Upper Reference Levels of Nutrients and Interpretation and Uses of Dietary Reference Intakes, and the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes. National Academy of Sciences Press, Washington D.C. http://www.nap.edu/catalog/10490.html?onpi_topnews090402.
- Schlanger S, Shinitzky M, Yam D. 2002. "Diet Enriched with Omega-3 Fatty Acids Alleviates Convulsion Symptoms in Epilepsy Patients." *Epilepsia* 43(1):103-4.
- Seddon JM, Rosner B, Sperduto RD, Yannuzzi L, Haller JA, Blair NP, and Willett W. 2001. "Dietary Fat and Risk for Advanced Age-Related Macular Degeneration." *Archives of Ophthalmology* 119(8):1191-9.
- Terry P, Lichtenstein P, Feychting M, Ahlborn A, Wolk A. 2001. "Fatty Fish Consumption and Risk of Prostate Cancer." *The Lancet* 357(9270):1764-6.
- Thompson, Tommy. 2001. Letter from Secretary of Health and Human Services in response to prompt letter regarding the trans-fatty acid content of food written by John Graham, Administrator of the Office of Information and Regulatory Affairs, Office and Management and Budget. November 26, 2001. Available at http://www.whitehouse.gov/omb/inforeg/hhs_prompt_ltr_comments.pdf.
- United States District Court of the District of Columbia. 2001. "Durk Pearson, et al. v. Tommy Thompson et al." Civil Action No. 00-2724. Memorandum Opinion written by Judge Gladys Kessler. May 9, 2001. Available at <http://www.dcd.uscourts.gov/00-2724.pdf>.
- United States Supreme Court. 2002. "Thompson, Secretary of Health and Human Services, et al. v. Western States Medical Center, et al. Certiorari to the U.S. Court of Appeals for the Ninth Circuit. No. 01-344. Available at <http://supct.law.cornell.edu/supct/html/01-344.ZS.html>.
- Willett, WC, Stampfer, MJ, Mason JE, Colditz GA, Speizer FE, Rosner BA, Sampson LA, Hennekens CH. 1993. Intake of *Trans* Fatty Acids and Risk of Coronary Heart Disease Among Women. *Lancet* 41:581-585.
- Zhang, J. S. Sasaki, K. Amano, and H. Kesteloot. 1999. "Fish Consumption and Mortality From All Causes, Ischaemic Heart Disease and Stroke: An Epidemiological Study." *Preventive Medicine*. 28:520:529.