HOW SHOULD HEALTH CLAIMS FOR FOODS BE REGULATED?

An Economic Perspective

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EXECUTIVE SUMMARY

New diet and health headlines seem to pop up every day. One day new evidence appears on oat bran and serum cholesterol. Another day brings news of calcium and osteoporosis. Nutrition has become a small-talk staple, which manufacturers are emphasizing increasingly in food labeling.

One might think a new emphasis on nutrition and health would be well received; labels that report National Cancer Institute (NCI) recommendations would seem to be more beneficial than labels that offer only games or product images. Nonetheless, health claims in food marketing are controversial. Many government regulators and consumer advocates believe that such claims are bound to be misleading. In fact, more health information had not appeared in food labeling earlier because the Food and Drug Administration (FDA) officially prohibited this use of health findings for many years.

Controversy over the FDA's ban on health claims was brought into sharp focus by Kellogg in 1984. At that time Kellogg began using All-Bran cereal boxes to inform people of some NCI advice about fiber and cancer. The NCI never questioned the accuracy of Kellogg's messages. Nevertheless, some FDA staff suggested that such labeling had transformed the breakfast cereal into a drug -- a drug being marketed illegally. While this stance may seem curious, it was not uncommon. For years the FDA had banned health information in food labeling by employing this argument. The FDA has not yet officially ruled on whether Kellogg's labeling made All-Bran an illegal drug. It appears that a final decision will not be announced until the

agency has had an opportunity to review and modify its overall policy on health claims in food labeling.

In August, 1987, almost three years after the All-Bran campaign began, the FDA published a notice of proposed rulemaking to revise its health claims policy. The notice signaled a major regulatory change. The value of labeling as a health information source had been formally recognized. No longer would the FDA threaten to react automatically to health claims by classifying the labeled food as a drug, thereby forcing the claims to stop. Soon the FDA was flooded with comments against this new policy. Many feared that it would trigger an outpouring of false and misleading claims.

Although the notice indicated that the official ban on health claims was being lifted, it did not indicate just how far away from a complete ban the FDA would be moving. More specifically, the 1987 notice is ambiguous about how much evidence about a diet-health relationship will be required before manufacturers can disseminate findings to consumers through labeling. This ambiguity leaves room for many different substantiation standards with very different implications for consumer welfare.

Two interpretations of the FDA's proposed substantiation standard have emerged. One approach is to require a fixed, pre-set level of substantiation for all claims, a level that approaches a "consensus" among experts. A contrasting approach relies explicitly on cost/benefit analysis. Under this more flexible "expected value" standard, the required level of substantiation depends upon the balance of likely costs and benefits associated with specific claims. Both polices prohibit claims that are clearly false or misleading. Both require that statements about diet and health research be accurate. Unlike the fixed consensus approach, however, the expected value

technique will allow some claims that are potentially valuable to consumers but do not yet rely upon undisputed evidence.

News leaks and recent statements by FDA staff indicate that the agency may adopt a rigid consensus standard. Our economic analysis suggests that this is likely to be a mistake because consumers could be denied accurate information and quicker product improvements. Potential consumer harm from rigid restrictions is illustrated by the following example. In 1988 the American Heart Association (AHA) unveiled a plan to allow food manufacturers to display an AHA seal of approval on foods that meet the AHA's nutritional standards for fat, cholesterol and sodium. Fees paid to the AHA by manufacturers that use the seal would finance a massive public education program on diet and health. The FDA, however, has not welcomed this innovative partnership between public health groups and business. Instead, the agency has reportedly warned that an AHA seal of approval on a label might constitute an illegal health claim.

An application of economic principles to the health claims debate suggests that consumers could probably benefit from programs like the AHA's. A frequent complaint is that consumers know too little about diet and health. Much of the problem lies in the economic nature of information itself. Weak property rights result in inadequate incentives for firms to disseminate general health information to consumers. Fortunately, there exists a countervailing market force. Profit incentives encourage food sellers to provide specific health information in food labeling. Health claims in labeling can lead to improvements in products as well as in consumer information. Thus the provision of health information by manufacturers can improve consumer welfare.

Unfortunately, profit incentives can also encourage manufactures to overstate the health value of their products. Thus, worries about potentially false or misleading claims cannot be dismissed on the basis of economic theory or common sense. Economic theory, however, does indicate that some market forces help to deter potentially deceptive claims. For example, firms that depend upon their good names to make repeat sales are unlikely to use inaccurate claims that could devalue their reputations. Furthermore, institutions such as the FDA and the Federal Trade Commission (FTC) exist to police the marketplace.

Policing the marketplace is admittedly tricky. Scientists rarely (if ever) know for certain that a substance such as fiber exerts a particular effect on a disease such as cancer. What science offers is a body of studies, each with its own limitations, which suggests (with varying degrees of certainty) that a particular diet/health relationship exists. Thus, regulators cannot simply allow claims about "true" diet/health relationships and prohibit claims about "false" diet/health relationships. Regulators must instead devise enforcement rules that explicitly account for the problems that arise when "truth" is unknown.

The application of basic cost/benefit principles to the health claims substantiation question suggests that the best way for the FDA to regulate claims surrounded by scientific uncertainty may be to adopt a flexible expected value rule. Such a rule could appropriately balance harm from allowing information about diet/health relationships that eventually proves to be false (Type I regulatory error) against harm from prohibiting information that eventually proves to be true (Type II regulatory error). In contrast, the fixed consensus rule, which has considerable support in the regulatory

community, dictates that only claims backed by a "consensus" of scientific agreement be allowed. This rule therefore implicitly assumes that harm from Type I regulatory error (harm from allowing claims about relationships that prove to be false) is more severe than Type II regulatory error (harm from prohibiting claims that prove to be true). Because both types of harm can be important, the expected value rule is preferable.

A case history suggests that serious Type II regulatory errors can be made. The FDA prohibited dietary cholesterol and fat content information in labeling for many years because a sufficient consensus had not been reached on the relationship between diet and heart disease. Now that a considerable consensus has emerged on the relationship between fat, cholesterol and heart disease, it appears that a Type II regulatory error, resulting in considerable consumer injury, was probably made. Consumers were denied information that now appears to be true -- information that might have led to beneficial dietary changes earlier. The FDA is not alone in making such errors. In our view, the FTC made a similar mistake when it negotiated a ban on tar and nicotine advertising in 1960 on the grounds that the hypothesis that reductions in tar and nicotine would improve health was not backed by a sufficient consensus.

The expected value principle, which requires that both Type I and Type II regulatory errors be weighed when making regulatory decisions, appears to be a feasible regulatory tool. For example, the FTC's advertising substantiation doctrine, now over fifteen years old, is essentially an application of the expected value rule. Under this doctrine the decision to allow or prohibit an advertising claim is based upon a comparison of the likely costs and benefits of each action. A rigid consensus of opinion is not

uniformly required to support accurate claims. Put simply, the FTC's policy allows manufacturers to use information surrounded by scientific debate as long as the scientific finding is accurately represented, the degree of evidence is not misrepresented, and the claim passes a rough cost/benefit test. Examples of how to structure a rough cost/benefit analysis for claims about saturated fat, serum cholesterol, and heart disease show how an expected value rule might be used today and how it might have been used twenty-five years ago.

The analysis presented in this report suggests that the FDA should consider adopting a substantiation standard similar to the FTC's. More specifically, the importance of weighing both Type I and Type II regulatory errors could be made clear in the agency's regulations. Otherwise, policy makers might find it too enticing to avoid controversy by maintaining the status quo through the use of a fixed consensus rule. Under an expected value rule, the FDA would be required to ask not only "How much harm would occur if Kellogg's claims caused consumers to eat a little more fiber, and science eventually shows that there is no link between fiber and cancer?" but also "How much good would occur if Kellogg's claims caused consumers to eat a little more fiber, and science eventually shows that eating fiber reduces the risk of cancer?" A consensus standard focuses too much attention on the former question and not enough on the latter.

An explicit requirement to consider harm from both types of regulatory errors would not prevent the agency from taking a compromise approach. The FDA could use a flexible substantiation standard in most situations, while reserving the right simply to prohibit claims when a preliminary cost/benefit analysis indicates that the potential danger from a subset of

claims is large, the science remains in substantial doubt, and the costs of careful assessment are high. The key, however, is to base all decisions on at least a rough cost/benefit analysis.

I. INTRODUCTION

On August 4, 1987 the Food and Drug Administration (FDA) published a notice of proposed rulemaking to revise its policy towards health information on food labels (health claims).[1] If adopted, this proposal would significantly alter the agency's official ban against disease prevention claims in food labeling. The full effect of the proposed policy remains unknown, in part, because many details are yet to be resolved. Much controversy has arisen over the proper way to interpret specific language in the 1987 proposal. Opponents of the change argue that it will harm consumers by unleashing a flood of false claims. They recommend abandoning the proposal or, at a minimum, adopting a restrictive interpretation. Proponents counter that change will benefit consumers by making important health information more accessible. They seek a more liberal reading of the language. Neither interpretation would allow unsubstantiated claims reminiscent of the patent medicine era, such as "Eat Product X and You Will Not Contract Cancer." The question to be decided is when to allow undeniably accurate statements such as "the National Cancer Institute believes that a high fiber, low fat diet may reduce your risk of some kinds of cancer" when reasonable, well-trained scientists disagree about the relationship between fiber and cancer.

The purpose of this paper is to analyze the FDA's proposed regulatory changes from an economic perspective. Section II sets the stage with a

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[1] The mention of possible relationships between food and a specific disease has come to be known as a "health claim." One example of a well-known health claim, discussed at length in this paper, is the NCI's belief that fiber consumption may be related to some types of cancer. At the outset it should be made clear that a "health claim" can be simply a reiteration of publicly available dietary advice.

review of the legal background and a summary of the events that led to the 1987 proposal. In particular, the relationship between the FDA's ban on health claims in food **labeling** and the scope of health information in food **advertising** is examined. Likely revisions to the 1987 proposal are also noted.

The economics of health information provision is discussed in Section III. This analysis focuses on how the incentives to provide diet and health information and the incentives to make product improvements change depending upon whether brand-specific characteristics and general health information can be combined in marketing messages.

Two rules for making decisions under conditions of scientific uncertainty -- the "fixed consensus rule" and the "expected value rule" -- are contrasted in Section IV. Under the fixed consensus rule no health claim is allowed unless a consensus exists about the existence of the underlying relationship between diet and health. For example, a manufacturer could not inform consumers that a research council advises that women may reduce osteoporosis risks by consuming more calcium unless a consensus of experts agree that a positive relationship between calcium and osteoporosis has been established. Thus information can not be used unless it is very unlikely that future research will overturn the finding.

In contrast, under an expected value rule, the calcium claim would be allowed as long as (1) the claim accurately portrays the research council's findings and (2) the expected net benefits of allowing a claim about calcium and osteoporosis, if the relationship is confirmed by future research, exceeds the expected net cost of allowing the claim, if future research overturns the finding. Because the expected value rule explicitly requires a comparison of

the costs and benefits of allowing a claim, it is more flexible than a consensus rule. We argue that this flexibility is necessary. More specifically, the expected value rule does not unduly emphasize harm from allowing claims about health relationships that are eventually proven to be false. It is also important to consider the potential harm from prohibiting information about health relationships that are eventually proven to be true. A review of prohibitions on cholesterol information illustrates that substantial harm can arise when consumers are denied accurate health information not yet backed by a consensus of scientific agreement.

Section V includes examples to demonstrate that an expected value approach is feasible. In particular, one example of an expected value rule is provided by the FTC's ad substantiation doctrine, which has been used for over fifteen years to determine when health claims should be allowed in advertising. The special difficulty of regulating health claims due to "ambient information," information that reaches consumers from sources beyond the control of government regulators and marketers, is also discussed in this section.

Conclusions are presented in Section VI. The FDA's 1987 proposal is judged to be an improvement over the agency's ban because it opens a "window" for manufacturers to convey accurate health information to consumers. Recent news leaks and statements from FDA staff, however, indicate that the window may not be opened enough to allow many accurate claims that could help consumers. More specifically, it appears that the FDA will require a broad consensus for all claims. The analysis here suggests that this would be a mistake. The best way to guard against potentially injurious claims would be to adopt an expected value rule similar to that

used by the FTC to analyze advertising cases. Unlike a fixed consensus standard, this more flexible rule does not injure consumers by placing more emphasis on harm from allowing claims that are shown by later research to be false than on harm from prohibiting claims that are shown by later research to be true.

II. BACKGROUND

A. FDA and FTC Authority Over Health Claims for Foods[2]

FDA authority over disease prevention claims in food marketing arises from the Food Drug and Cosmetic Act (FDC Act), which prohibits the sale of misbranded foods or drugs in interstate commerce.[3] The use of health information (health claims) in food labeling can cause a food to be misbranded in two ways. Section 403 (a) of the FDC Act dictates that

> A food shall be deemed to be misbranded if . . . its labeling is false or misleading in any particular . . .[4]

Thus, a health claim that is judged to be misleading can lead to a misbranding charge. The use of health information in food labeling can also cause a food to be misbranded if the FDA uses the claims to classify a food as a drug. Section 201(g)(1)(B) defines the term "drug" to include

> articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals.[5]

The use of disease specific information in promotional materials could therefore turn a common food into a drug. Such "drugs" would typically be misbranded because foods rarely meet the extensive labeling and testing

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[2] This paper is limited to health claims for conventional "foods", which are already a safe and standard part of the food supply. Claims for vitamin or mineral supplements are not examined here.

[3] For a more complete analysis of FDA and FTC jurisdictions over health claims for foods see Taylor (1988) and Hutt (1986).

[4] 21 U.S.C. § 343.

[5] 21 U.S.C. § 321.

requirements imposed upon drugs. Misbranding charges are serious because they can result in seizure of the product by the FDA.

The FDA's explicit authority over labels and associated promotional materials[6] can also influence advertising because the agency can look to claims made for the product in advertising to decide whether a food is being promoted as a drug. The agency has frequently exercised its power to prohibit claims related to disease prevention and the agency has often reminded the food industry of the potential regulatory consequences of making such claims in any promotional material, including advertising.[7] Manufacturers have apparently believed that the FDA could and would take action based not only on claims in labeling but also upon claims made in advertisements.[8]

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[6] More specifically, Section 201(m) of the FDC Act specifies that

> The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

21 U.S.C. § 201.

[7] For example, Hutt indicates that the FDA's ban on health claims in labeling may have impeded some advertising claims. He writes that the FDA

> . . . took the position that any product for which drug claims were made in advertising became a drug as well as a food, whose label must bear the adequate directions for use required for a drug under Section 502(f) of the FD&C Act. This position, commonly referred to as the "squeeze play," was upheld by the courts. More recently, FDA took the position that a nutrition claim made solely in advertising is sufficient to trigger mandatory nutrition labeling under the FD&C Act.

Hutt (1986) at 25-26.

[8] In response to the FTC's request for comments on its advertising substantiation program in 1983, Kellogg noted that even if the FTC were to allow accurate claims about fiber and health in advertising "it would undoubtedly be attacked by the Food and Drug Administration as making (continued...)

Under the same theory, the FDA has also prohibited claims that make no explicit mention of a particular disease, but are clearly disease-related.[9] For example, based on this reasoning, manufacturers were prohibited for many years from accurately listing polyunsaturated fat content on food labels.[10]

FTC authority over health claims for foods stems from two sections of the Federal Trade Commission Act (FTC Act). Section 12 of the FTC Act gives the FTC explicit authority over food advertising, specifying that

> It shall be unlawful for any person, partnership, or corporation to disseminate, or cause to be disseminated, any false advertisement . . . by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase in or having an effect upon commerce of food, drugs, devices, or cosmetics.[11]

Section 5 of the FTC Act, which applies to all advertising and not just to that for foods, specifies that ". . . unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful."[12] A central principle in FTC law is that if advertising claims are not adequately substantiated they will be regarded as deceptive or unfair. Moreover, ads that specify a particular level of substantiation must be backed by that level of

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[8] (...continued)
impermissible drug claims." Moreover, it appeared to Kellogg the FDA's "policy of attacking all advertising or labeling, which mentioned the name of a disease, would have to be changed" before manufacturers could discuss the current state of scientific data about food and health in advertising. Haefner (1983).

[9] For example, in 1979 the FDA declared its intention "to maintain the present policy of not allowing disease-related claims to appear on the labeling of conventional food products" but promised to "reexamine this policy if the need arises." 44 Fed. Reg. 76,007 (1979).

[10] This is discussed further in Section IV(D).

[11] 15 U.S.C. § 52.

[12] 15 U.S.C. § 45.

substantiation. Thus a claim that "a survey of nutritionists indicates that most nutritionists recommend using Brand X oil, because it has less saturated fat than any product in its class," must be backed by a sound survey.[13] Firms are required to have a "reasonable basis" for less explicit claims.[14]

To address the possible confusion and inefficient resource allocation stemming from overlapping jurisdiction between the FTC and the FDA, the two agencies entered into a Memorandum of Understanding.[15] According to the memorandum, the FTC has primary responsibility with respect to the truth or falsity of all advertising (other than labeling) of food. The FDA has primary jurisdiction over all matters regulating the labeling of food. The memorandum also notes that liaison activity will be required when "the same or similar claims are found in both labeling and advertising" and when "written, printed or graphic material may be construed as either advertising or as accompanying labeling or both, depending upon the circumstances of distribution." The memorandum therefore acknowledges the inescapable problem of sometimes distinguishing advertising from labeling.

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[13] The underlying representation must also be truthful and not deceptive. For example, see Standard Brands, Inc., 97 F.T.C. 233 (1981).

[14] The FTC's deception and advertising substantiation policy statements express what is needed for ads to pass muster under the FTC Act. Both statements have been adopted in Commission decisions: Deception Policy Statement, appended to Cliffdale Associates, Inc., 103 F.T.C. 110, 174-84 (1983); Ad Substantiation Policy Statement, appended to Thompson Medical Company, 104 F.T.C. 648, 839-42 (1984), aff'd, 791 F.2d 189 (D.C. Cir. 1986). The reasonable basis standard is explained more fully in Section V(A).

[15] 36 Fed. Reg. 18539 (1971).

B. Kellogg: Harbinger of Change

The FDA's prohibitions on health claims in food marketing were brought into sharp focus by Kellogg's 1984 marketing campaign for All-Bran based on National Cancer Institute (NCI) proclamations about diet and cancer.[16] One All-Bran print ad began with the following statement in bold print: **"At last some news about cancer you can live with."** It then continued:

> The National Cancer Institute believes a high fiber, low fat diet may reduce your risk of some kinds of cancer. The National Cancer Institute reports some very good health news. There is growing evidence that may link a high fiber, low fat diet to lower incidence of some kinds of cancer. That's why one of their strongest recommendations is to eat high fiber foods. If you compare, you'll find Kellogg's All-Bran has nine grams of fiber per serving. No other cereal has more. So start your day with a bowl of Kellogg's All-Bran or mix it with your regular cereal.[17]

The ad also included a graph comparing the fiber in Kellogg's All-Bran to that in other high fiber foods and informed consumers that "for a free booklet with more preventative tips, write Box K., National Cancer Institute, Bethesda, MD 20814." Essentially the same claims were made on the product label, which also listed a toll-free number to call for further information.

Some FDA staff reportedly responded to the product labeling "by suggesting that the claims make the product a drug and in any event are misleading."[18] In contrast, Carol Crawford, then Director of the FTC's

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[16] This campaign began in October 1984 with package labels and print and TV ads. (New York Times, Feb. 19, 1986 at C-1.)

[17] Crawford (1984).

[18] See Hutt (1986) at 48. Kellogg maintained that neither labels nor ads for All-Bran made health claims, but instead merely printed the claims made by the National Cancer Institute. (New York Times, Feb. 19, 1986, beginning at (continued...)

Bureau of Consumer Protection, explained why she supported the advertising in a speech to the American Advertising Federation. Her explanation focused on the express claim that the NCI believes a high fiber, low fat diet may reduce the risks of some kinds of cancer:

> It is a claim containing express support for a statement about a possible -- not certain -- way to reduce -- not eliminate -- the risks of some -- not all -- kinds of cancer.[19]

In Crawford's view, the express claim was adequately substantiated. She noted that

> In fact, we understand that Kellogg consulted the NCI when it developed the ad and that the NCI was satisfied that the statement accurately portrayed its findings. This is, no doubt, reflected in the careful qualifications included in the text of the advertisement. Moreover, the qualifications are integrated into the claim itself . . . Thus, the ad has presented important public health recommendations in an accurate, useful and substantiated way. It informs the members of the public that there is a body of data suggesting certain relationships between cancer and diet that they may find important.[20]

The NCI's involvement in All-Bran's labeling and advertising further complicated any regulatory response from the FDA. Like NCI, the FDA is

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[18] (...continued)
C-8.) FDA staff nonetheless publicly stated that the Kellogg All-bran ads violated FDA rules, but Commissioner Young asked the staff to reconsider FDA policy rather than bring a case. (New York Times, Feb. 19, 1986 at C-8.) In fact, FDA top management was sympathetic to the Kellogg campaign, but FDA staff was considerably more suspicious. (Advertising Age, Dec. 9, 1985 at 3.)

[19] Crawford (1984).

[20] Ibid.

part of the Department of Health and Human Services.[21] The FDA therefore faced opposing views from individuals at two federal agencies.

The FDA did not officially rule on whether All-Bran had been transformed from a food into an illegal drug by virtue of the health information in its labeling. A formal decision appears unlikely until the agency completes a thorough re-evaluation of its general policy toward health claims for foods.[22] This review is discussed later in this section.

C. Marketplace Reaction

The decision by the FDA not to proceed immediately against Kellogg was widely reported as a major departure from a long-standing FDA policy that triggered a vigorous market reaction.[23] Within a week after the All-

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[21] An NCI spokesman noted that for a government agency prohibited from buying air time, "The opportunity to work with an organization like Kellogg is attractive." (Advertising Age, Oct. 29, 1984 at 6.) Speaking before a recent health claims conference, Stanford A. Miller, Ph.D., former Director of the Center for Food Safety and Applied Nutrition at the FDA, recounted the relationship between Kellogg and NCI. He concluded that nobody will ever know the extent to which NCI planned the campaign with Kellogg. However, it is clear that NCI did cooperate with Kellogg. See Miller (1987). The relationship between Kellogg and NCI is also discussed in Freimuth et al. (1988).

[22] Food Chemical News May 16, 1988 at 13-14.

[23] Health claims for foods had surfaced before 1984. Earlier, less well-known health claims appeared: (1) in radio advertisements during 1982 in the Chicago area for a brand of distilled water, which cited a Council on Environmental Quality finding of a link between chlorinated water and cancer (the ads were apparently poorly received and soon dropped); (2) in Kellogg ads in 1982 for Nutri-Grain cereal citing a National Academy of Sciences study recommending whole-grain cereals as a part of a cancer-prevention diet; and (3) in a Quaker Oats ad stating that "medical studies" indicate that eating oat bran could reduce cholesterol. See Advertising Age, October 29, 1984 at 85; on the earlier Kellogg ad, also see Advertising Age, July 5, 1982; on the Quaker ad, also see Food Chemical News, Jan. 6, 1986 at 11. Also see Hopper (1986), who cites General Foods ads in 1980 on the federal government's dietary guidelines.

Bran campaign began, NCI reported that a number of other major food marketers were investigating ways to use similar diet-cancer relationship information in their advertising.[24]

Within the cereal market, Kellogg's competitors responded by introducing new cereals with more fiber[25], adding fiber to existing cereals, and advertising these changes. The effect of the new ads on the sales of high-fiber cereals was estimated by Levy and Stokes, who found that within a year after the All-Bran campaign, sales of all high-fiber ready-to-eat cereals had increased by 37%, and high-fiber products had increased their relative share of the total cereal market from 6.1% to 8.4%. This growth was partially offset by a decline in the sales of granola cereals.[26]

The apparent effects of the health claims for fiber products has extended beyond market shares and product quality to encompass more detailed information about the relationships between fiber and health. For example, a Kellogg's Common Sense Oat Bran label emphasizes the importance of soluble fiber:

> Enjoy foods that are low in saturated fat and those that contain "soluble" dietary fiber (some experts believe that soluble fiber may prevent absorption of substances that are made into cholesterol in your body).[27]

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[24] See "All-Bran ads may inspire health trend," Advertising Age, October 29, 1984 at 6.

[25] Freimuth et al. (1988) note that during the Kellogg campaign eight new bran cereals were introduced. Further analysis of increases in the fiber content of cereals can be found in Ippolito and Mathios (1989).

[26] Although it seems likely that at least part of this change resulted from the health information, some of the estimated shift may have resulted from simultaneous changes in prices and promotions, which were not accounted for in the study. See Levy and Stokes (1987).

[27] This message is part of a label that features Dr. Art Ulene and the American Medical Association's "Campaign Against Cholesterol."

This label also goes one step further to encourage consumers to improve their health by including a coupon for a $5.00 refund on a cholesterol screening.

D. FDA's Review: Process and Proposed Rule

Soon after the All-Bran campaign was launched, Joseph P. Hile, FDA's Associate Commissioner for Regulatory Affairs, outlined the agency's likely policy response. Hile stated that the public could benefit from accurately represented health claims if the claims were supported by a "consensus" within the medical and scientific community, and that accordingly, the FDA would allow such claims on food labels (and by implication, in advertising). Claims not supported by a consensus, however, would cause the product to be regulated as a drug.[28]

On August 4, 1987 the FDA published in the Federal Register[29] a notice of proposed rulemaking with a substantiation standard that appeared somewhat less restrictive than the consensus standard articulated earlier by Hile.[30] The 1987 proposal has three main parts. First, the introduction explained the FDA's belief that, under some circumstances, consumers can

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[28] Hile (1986).

[29] 52 Fed. Reg. 28,843.

[30] One possible explanation for the apparently less restrictive standard is discussed in an April 6, 1988 report of the House Committee on Government Operations resulting from hearings held by Chairman Weiss' subcommittee on Human Resources and Intergovernmental Relations. The report alleges that "OMB inappropriately intervened in the health claims policymaking process" and that at OMB's insistence, FDA dropped a "consensus" requirement from its health claims proposal. See U.S. Congress (1988).

benefit from health information in food labeling.[31] Next, the FDA's proposed policy toward such information was outlined. Finally, changes were proposed to make the Code of Federal Regulations consistent with the new policy.

The proposed regulatory amendments stated that the FDA "will not consider the food to be a drug . . . solely because the labeling contains a health-related message" if:

(i) The claim is truthful and not misleading;

(ii) The claim is supported by valid reliable, publicly available scientific evidence derived from well-designed and conducted studies consistent with generally accepted scientific procedures and principles performed and evaluated by persons qualified by expertise and training in the appropriate disciplines;

(iii) The claim is consistent with generally recognized medical and nutritional principles for a sound total dietary pattern; and

(iv) The food is labeled in accordance with the requirements of this [nutritional labeling] section.[32]

The preamble to the proposed amendments explained that to be "truthful and nonmisleading," a claim must rely upon substantiation meeting the following standards:

> Preliminary findings should be confirmed. Conclusions supported by a less-than-clear data base may prove in time to be correct but are not appropriate for use on food labeling if they do not reflect the weight of scientific evidence.[33]

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[31] In support of FDA's contention that health claims have potential benefits reports such as the following are cited: "Healthy People," The Surgeon General's Report on Health Promotion and Disease Prevention, DHEW (PHS) Publication No. 79-55071; and "Promoting Health/Preventing Disease: Objectives for the Nation," Department of Health and Human Services, Public Health Service, November 1980.

[32] 52 Fed. Reg. 28,849 (1987).

[33] Ibid. at 28,845.

Although the preamble emphasizes that the various criteria apply directly to labeling rather than to advertising,[34] it specifies that the proposed changes "do not change FDA's basic interpretation of the act or legal precedent in cases of false or misleading claims."[35] It therefore appears that the FDA was planning to continue to assert its authority to consider claims in all types of promotional material when deciding whether a food should be classified as a drug.

Two likely interpretations of the substantiation requirements articulated in the 1987 proposal have emerged. The reference to "well-designed . . . studies" is reminiscent of the FTC's ad substantiation standard, which may allow accurate claims based on only one or two competent studies. In contrast, the reference to confirming preliminary findings with the "weight of scientific evidence" suggests a more stringent standard approximating a consensus requirement.

FDA staff comments made shortly after the 1987 proposal was published indicated that the agency was likely to adopt a consensus standard. Addressing a September 1987 conference on health claims, Frederick H. Degnan, the FDA's Associate Chief Counsel, characterized the substantiation standard in the 1987 proposal as closer to the "general recognition" standard traditionally used by the FDA than to the FTC's substantiation standard.[36]

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[34] The notice explains that FDA's evaluation criteria "will apply to health claims made on food labels but not to health claims made in food advertising, except in those limited circumstances which fall under the labeling provisions of the act." 52 Fed. Reg. 28,845.

[35] Ibid. at 28,845.

[36] Food Chemical News, Sept. 21, 1987, at 6; Degnan was speaking at a conference entitled "Health Claims For Foods--Where Are We Now?", sponsored by the Food and Drug Law Institute, September 10, 1987.

In addition, Dr. F. Edward Scarbrough, Deputy Director of the Office of Nutrition and Food Sciences in FDA's Center for Food Safety and Applied Nutrition remarked that the agency felt some form of consensus was needed to substantiate claims.[37]

More recent reports in the trade press further suggest that a consensus requirement is likely. Food Chemical News reports that a final proposed rule submitted to OMB would

> allow use only of model label statements for specific health-related issues, for which scientific summaries and consumer health message summaries have already been developed and reviewed by the Public Health Service's Committee on Health Messages.[38]

In addition, the proposed final rule reportedly also cautions that manufacturers who extend "development of health-related statements to topics other than those described in this document will run a substantial risk of regulatory action."[39]

E. Public Reaction and Needed Analysis

The FDA's August, 1987 proposal suggested that the agency was moving toward a regulatory regime in which regulation of health claims in food labeling would be less strict than under previous FDA policy, but more strict than the FTC's regulations for food advertising. An outpouring of controversy soon followed. By October, 1988 the FDA had received 518 formal comments on the proposal.[40]

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[37] Ibid. at 7.

[38] Food Chemical News November 28, 1988 at 51.

[39] Ibid.

[40] Telephone inquiry to Dockets Management Branch, Food and Drug Administration, October 27, 1988.

The proposed change generated considerable negative comment from individuals who support the traditional ban on health claims. A New York Times editorial exclaimed:

> Just when knowledge has been gained of how proper diet can reduce heart disease and cancer, the Administration proposes to let industry unleash a babble of misleading claims that will let bad foods masquerade as good. If the Food and Drug Administration cannot write better rules, it had better continue the ban on health claims by writing none.[41]

Among many comments opposing the 1987 proposal were those filed by the American Institute of Nutrition and the American Society for Clinical Nutrition. Both groups maintain that claims about specific diseases only confuse consumers and recommend that the FDA banish such claims from food labels.[42] Manufacturers that stand to lose sales by further information on the possible links between diet and health also oppose the change.

Opposition has also appeared in Congress. The U.S. House of Representative's Committee on Government Operations recommended that HHS:

> Enforce existing law by requiring premarket approval of any food labeled as effective in the diagnosis, cure, mitigation, treatment, or prevention of disease, as decreed by . . . the Food, Drug & Cosmetic Act, unless such food is Generally Recognized as Safe and Effective for such use . . . The Department should immediately take all necessary steps to revoke all aspects of current regulatory policy that are in conflict with this recommendation.[43]

Others have supported the FDA proposal, in some cases arguing that it is still too restrictive. Support comes from the National Food Processor's

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[41] The New York Times, October 10, 1987 at A-18.

[42] Medical Advertising News, Jan. 15, 1988 beginning at 26.

[43] U.S. Congress (1988) at 36.

Association (NFPA). In a Citizens Petition predating the publication of the proposed policy, the NFPA argued that the FDA's ban on truthful and nonmisleading health claims conflicted with Congress's mandate to educate the public about nutrition and health.[44] The National Nutritional Foods Association argues that the FDA's proposed "weight of scientific evidence" standard is an improvement but it should not be so restrictive as to "be interpreted as assent by the majority of FDA-recognized authorities."[45] Nutritionist Kristen McNutt believes that the time has come for a freer flow of information. Her belief is based, in part, on "a trust that, in the final analysis, consumers in general have more common sense than they are credited with having."[46]

The health claims debate has generally excluded a careful analysis of the economic aspects of policy toward health claims for foods. Supporters of a complete ban on health claims usually assume that any relaxation of the ban would bring a flood of false or grossly misleading claims reminiscent of the patent medicine era. This fear seems unfounded in view of the regulatory apparatus that will remain in place -- the FTC, for example, requires that advertisements be adequately substantiated.[47] More

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[44] "NFPA Citizens Petition" to Frank E. Young, M.D., Commissioner of Food and Drugs, May 13, 1985.

[45] "Submission of the National Nutritional Foods Association Concerning Food and Drug Administration Proposed Regulation 21 CFR Sections 101.9 [i] and [j]: Health Messages," Docket No. 85N-0061, January 4, 1988.

[46] McNutt (1988) at 46-47.

[47] The FTC's policy is described in Section V(A).

importantly, there are compelling reasons to believe that a market that includes health claims subject to a standard like that currently used by the FTC would be superior to one in which all such information is prohibited.

III. THE ECONOMICS OF HEALTH INFORMATION

A few important points often get lost in the health claims debate because they are not obvious until the debate is analyzed from an economic perspective. First, because information has peculiar economic properties, the incentives to provide consumers with the optimal amount of nutrition information are weaker than the incentives to provide consumers with the optimal amount of most other goods. Thus, even without a government imposed ban, consumers are not likely to have as much diet and health information as they want. Second, this incentive problem can be overcome considerably by allowing manufacturers to combine generic nutrition information with specific product information in marketing messages. Third, unless manufacturers are allowed to explain the likely health benefits of their products, they have little incentive to produce more healthful products. Finally, a review of the costs and benefits of allowing health claims suggests that an outright ban would not be in the public interest.

A. Weak Incentives to Supply Generic Health Information to Consumers

Statements about diet and health that are not connected to a particular product or brand constitute "generic" health information. The peculiar economic properties of information affect the generation and dissemination of such information by markets and, hence, the impact of marketing regulations on consumers.

"New" information -- for example a finding that the risk of breast cancer may be reduced by eating less polyunsaturated fat -- is valuable and,

in principle, could be sold to consumers. In practice, however, the opportunity to market such information is undermined because information is a "public good." This characteristic impedes the profitable sale of information and tends to cause markets to produce less than the efficient amount of information. As a "public good," information, unlike a cake, is not used up when it is "consumed." In other words, your use or "consumption" of information does not prevent anyone else from using the same information. Therefore, any sale of information actually creates a competing source of that information.

A related problem is that property rights to information are weak. Information is easily transmitted from one individual to another, and sellers usually cannot monitor the use by others of the information they produce. Attempts to prevent the unauthorized spread of information are often futile.[48] This predicament is often referred to as the "free-rider" problem because those who do not purchase information can "free-ride" on the purchases of others.

The free-rider problem makes it difficult for an information producer to profit from the sale of information. The incentives to produce information are therefore too weak, in the sense that no one has an incentive to produce as much information as would be optimal in the economic sense i.e., to the point where its marginal benefit to society equals its marginal cost.

Once information is produced, market incentives to disseminate the information are also weak. For example, dissemination of information by television is restricted by the inability of the purveyors of information to

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[48] Copyright law protects the words used to express information, but not ideas or summaries drawn from written information. Thus legal means for preventing use of information is weak.

charge directly (except with pay TV) for their services. Perhaps more importantly, those who repackage information to reach subsets of the general population face the same free-rider problem as those who originally produced the information.

Food manufacturers face additional disincentives to produce and disseminate health information. Information supplied through advertising may not be believed by consumers, thus undermining the incentives to initiate marketing programs that supply generic health information.[49]

These economic characteristics of information tend to deter firms from producing and disseminating as much generic health information as society is able and willing to pay for. Moreover, this deterrence effect exists even in the absence of regulatory restrictions on the use of health information in food marketing.

Despite these disincentives, some health information will reach consumers. Journalists and health educators, who typically do not compensate the original producers of information, bring some diet and health news to consumers. Researchers continue to produce new information even though they typically are not fully compensated for their efforts. The government augments information produced and disseminated in the private sector with its own research programs and public information programs. (To some extent, these programs compensate for government restrictions against the flow of health information through some channels).

These private and government efforts to inform consumers about diet and health have apparently been inadequate. A look at public opinion polls

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[49] See Hirshleifer and Riley (1979) and Beales, Craswell and Salop (1981). For a brief review of information in the context of advertising regulation, Ford and Calfee (1988).

suggests that when it comes to the topic of diet and health, consumers are often misinformed and want more information.[50] Large-scale initiatives recently undertaken to improve the nutrition IQ of consumers further support this conclusion (if consumers were already well-informed there would be no incentive to fund more information programs). For example, the American Heart Association (AHA) is planning to offer its seal of approval for processed foods that meet its nutritional standards for fat, cholesterol and sodium. According to the plan, manufacturers will pay independent labs to evaluate product content. Manufacturers will be able to purchase the right to use the AHA seal of approval on products that meet the AHA standards. Fees paid to the AHA will then fund an extensive public information program on the relationship between food and health.[51]

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[50] For example, approximately 70% of those questioned in a recent survey knew that cholesterol and fat affect coronary heart disease risk, but only 38% knew that cholesterol and fat are different substances. The survey was conducted in 1986 by the FDA in conjunction with the National Heart, Blood and Lung Institute using a national probability sample. (Telephone conversation with J.T. Heimbach, FDA, April 16, 1987. Results later published by Schucker, et al., 1987.) The same survey also showed that only 29% of consumers know that a product described as cholesterol-free could still be high in saturated fat. Only 11% of those surveyed correctly knew that hydrogenation made a fat more saturated. More than twice as many consumers (27%) thought it made a fat less saturated. (Lecos, 1988.) Also, according to a national consumer survey conducted by the Gallup Organization in 1985, 68% of those surveyed indicated that they would like more information about nutrition. (Results of "The Gallup Study of Changing Food Preparation and Eating Habits," Princeton, N.J., The Gallup Organization Inc., as reported in Lord, Eastlack, and Stanton, 1987.) Care must be taken, however, when interpreting figures such as these; consumers may overstate the value of information when responding to such survey questions.

[51] Washington Post Health, January 17, 1989 at 16. According to this article, the FDA "has warned that an AHA seal on a label that endorses a particular food product might constitute an illegal, unproven health claim."

B. Marketing as a Source of Health Information

The weakness of incentives to supply generic health information leaves an important informational role for the use of product-specific health information in food marketing. Health information produced by others can be used by food manufacturers as a marketing tool. In fact, even public health authorities can find commercial advertising to be a useful supplement to their own efforts. An example is the production of fiber-cancer information by NCI and the dissemination of NCI's findings by Kellogg through advertising and labeling.[52]

The dissemination of health information through marketing, however, is affected by many of the same economic difficulties that impede the flow of generic information through other channels. Free-riding occurs, for example, when an ad that says "look for high-fiber cereals to help follow the NCI's recommendations for fiber and health" benefits all high-fiber cereal producers, not just the company that pays for the ad.[53] This sharing of benefits reduces a seller's incentives to provide such information.

Sellers can alleviate the free-rider problem in various ways. Collective advertising by trade associations is one fairly common remedy for certain products, such as grapes. This is not a complete solution, however, because associations inevitably encounter difficulty in "taxing" firms to support the

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[52] See Section II(B) for a discussion of what is known of NCI cooperation with Kellogg on launching the All-Bran ads in 1984.

[53] Actually, the cereal seller may wish to communicate two distinct pieces of information: the significance of fiber and the relative advantages of cereal in this respect. The first piece of information, relating to fiber and disease, imposes the more serious free-riding problem because information on the effects of fiber apply not only to all cereals but to other foods as well (for example, bread and vegetables).

advertising. Even within trade associations, there is an incentive for some firms to free-ride on the contributions of other firms.

Another remedy, available to individual advertisers, is to link health information to a specific brand rather than to a product category: "Ajax cereal is high in fiber, and NCI has made the following recommendations about fiber and health . . ."[54] Such claims provide an incentive to create branded products where only "generic" products had previously been available. Within the chicken industry, for example, the advent of brand names attached to nutritional information has provided an easy way for sellers to mitigate the free-riding problem from reducing fat and disseminating information on fat content.[55] Relatively large firms are more likely to adopt this strategy because the larger the market share of the seller, the larger will be its share of the benefits.[56]

A third technique is to make comparative claims based on relatively small differences among products. Such claims associate the marketer with

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[54] This ad approaches a false "implied uniqueness" claim by suggesting that only Ajax cereal provides the benefit of fiber. Such claims are common; one might cite advertisements for Tylenol and other branded acetaminophen that emphasize the lack of aspirin's side effects, or for that matter any aspirin ad that omits the fact that other aspirin also relieves pain. Implied uniqueness claims have occasionally been attacked by policy analysts. It seems clear, however, that such ads may confer benefits because they allow useful claims to be made that would not be made if they had to be phrased so as to apply to competing products as well as the advertised brand. See Ford and Calfee (1988).

[55] For a discussion of the importance of brand names in meat marketing see The Wall Street Journal, January 4, 1989 at A1-A2. Brand names are thought to have been a boon for chicken producers and more branding of beef has been suggested as a means of increasing beef demand.

[56] Dominant firms, however, are less likely to advertise negative attributes because any decline in total demand caused by the knowledge of negative product characteristics would hurt the dominant firm more than its smaller competitors.

progress on the advertised positive attribute. Focusing product competition on a firm's health advantages may then reinforce the importance of the attribute for health and create incentives for product improvements throughout that entire industry.[57]

C. Potential Benefits of Health Claims

Health claims can ignite a chain reaction beginning in the consumer side of the market (first-order effects) and then moving to the firm side of the market (second-order effects). The primary first-order benefit is to disseminate limited, concise health information to consumers, which can heighten consumer interest in such information by decreasing the cost of searching for nutrition information. This effect alone could be important. Specific marketing initiatives to bring diet and health information to consumers illustrate the importance placed on this effect by manufacturers and government alike:

> NCI and Kellogg cooperated to bring fiber-cancer information to consumers;
>
> NCI and the Giant supermarket chain in the Washington, D.C. area cooperated to encourage consumers to reduce cancer risk by making dietary changes away from fat and toward vegetables and other fiber sources;[58]
>
> The director of marketing at Hoffman-LaRoche, a pharmaceutical firm, recently said that probably the single most important factor in getting consumers to understand and respond quickly to lowering their intake of saturated fat has been the advertising being done by the fats and oils manufacturers;[59] and

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[57] Product improvements related to health information in marketing are discussed in the next section.

[58] Food Chemical News, March 9, 1987 at 52.

[59] Food Chemical News, March 31, 1986 at 35.

> A dental researcher noted, "All this attention [to plaque reduction] is good; it creates an atmosphere where people pay more attention to oral hygiene."[60]

Another first-order benefit is that health claims in marketing can reduce the costs to consumers of obtaining additional health information. Information has two cost components: (1) the out-of-pocket expense of purchasing information (for example the price of a book or magazine) and (2) the value of time spent searching for, absorbing, and understanding the information.[61] By reducing the costs to consumers of acquiring health information, the value of health-related marketing messages can extend beyond the information presented in the message, *per se*, and be a catalyst for inducing consumers to seek further information. For example, tens of thousands of consumers responded to the All-Bran campaign by calling an 800 number maintained by NCI to request further information on diet and health.[62] Moreover, marketing messages may be an effective way to communicate with sub-populations that are not typically reached by other information sources. For example, the demographic characteristics of people who called NCI because of the All-Bran campaign differed markedly from

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[60] Dr. Irwin D. Mandel, director of the Center for Clinical Research in Dentistry at Columbia U., as quoted in Newsweek, October 28, 1985 at 76.

[61] For more information on the cost/benefit approach to information acquisition, see Caves (1986).

[62] By October 1986, over 70,000 consumers had called the information hotline provided by the Kellogg All-Bran label to get further information from the National Cancer Institute. Food Chemical News, October 6, 1986 at 20.

those who had typically called NCI.[63] Clearly, health care costs can be reduced if better informed consumers choose more healthful foods.

The second-order benefits extend beyond consumers themselves. These effects can be divided into two categories: (a) improvements in the research that underlies health claims, and (b) improvements in product quality.[64]

The ability to use health information in marketing makes the information itself more valuable, in effect increasing the demand for (and the supply of) health research.[65] The cigarette market of the 1950s provided a vivid example of the connection between advertising based on health information and health-related product research. Background information in the form of public reports on the tar and nicotine content of cigarettes triggered a vigorous "tar derby," i.e., a surge of advertising that featured tar and nicotine claims. The tar derby, in turn, helped to motivate roughly a 40% reduction in nicotine between 1956 and 1960. This dramatic reduction occurred despite expert testimony, as late as 1951, that such reductions were technically impossible. Similarly, between 1957 and 1960 the sales-weighted tar average for filter cigarettes declined by approximately 31 percent.[66]

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[63] Freimuth, Hammond and Stein (1988) report that the campaign increased the number of calls from the general public and that blacks responded more to the ads than to the labels.

[64] Another possible second-order effect is a change in market structure. We shall not discuss changes in market structure, in part, because it is difficult to predict whether such changes translate into net costs or benefits. History yields at least two examples of market structure changes emanating from health information in marketing: the advent of Crest fluoridated toothpaste and the rise of filtered cigarettes, both of which brought drastic changes in market shares.

[65] Calfee (1985) and (1986). Also see Mulholland (1988).

[66] Mulholland (1988).

In contrast, the rate of health improvements in cigarettes (most notably in filter tip cigarettes) slowed soon after 1960 when the FTC negotiated a voluntary agreement with the industry that eliminated all tar and nicotine claims in cigarette advertising. In fact, improvements over the next 15 years would not match those made between 1956 and 1960. The ban, which reduced the incentive to make product changes, appears to have retarded product research as well. According to a 1963 article in Reader's Digest, which had been a major source of tar and nicotine data during the 1950s, "When the 'tar derby' ended, so did research for safer cigarettes."[67]

Health advertising can also affect the quality of competing brands or product lines that do not make health claims because competitors can free-ride on the health claims of an industry leader. For example, after Kellogg advertised the NCI results on fiber and cancer, All-Bran sales increased rapidly. When competition increased in the high fiber cereal market, Kellogg was compelled to increase the fiber content of All-Bran. Competitors further improved their offerings and even non-cereal fiber products prospered.[68] Not all of these competitors used the fiber-cancer message.

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[67] "Report to Consumers", Reader's Digest, August 1963 at 99 as cited in Calfee (1985) at 49.

[68] The Kellogg All-Bran campaign began Oct. 7, 1984 and by April 1985 the fiber war was well developed, including the improvements in All-Bran and competing brands. All-Bran sales increased 41% in the first quarter after the campaign began, and that sales of higher fiber cereals generally increased greatly during the ensuing months. Wall Street Journal, April 2, 1985. The effect of Kellogg's health claims for All-Bran on fiber consumption and fiber content is analyzed thoroughly in Ippolito and Mathios (1988). They find that cereals introduced following the All-Bran campaign were higher in fiber than the average cereal available before the campaign began. In addition, their evidence suggests that cereal advertising also led to an increase in the amount of fiber consumed through bread.

Some simply noted that their product contained fiber and relied on others to make the fiber-cancer connection.

Numerous examples attest to how quickly product quality adjusts to new information:

> Improved toothpastes and other dental products have emerged from plaque reduction claims;
>
> Sodium content has been reduced in some antacids and in many foods; and
>
> Beef substantially lower in fat and cholesterol has become available through the use of new breeding and feeding techniques and from closer trimming at supermarkets.[69]

D. Potential Costs of Health Claims

The costs of health claims, like the benefits described earlier, can be classified into first-order and second-order effects. First-order costs flow directly from misinformation. When claims are false or misleading consumers will tend to pay more for foods incorrectly believed to be relatively nutritious. They may also change their eating habits in ways that increase rather than decrease health risks. Risks increase when relatively harmful, rather than relatively healthful foods are consumed, or when beneficial therapy for illness is forgone.

False or misleading claims impose serious second-order costs on the market for information itself. If consumers learn that certain claims are false, the credibility of all claims may be reduced. A loss in credibility would undermine the power of marketing to bring important truthful nutrition information to consumers.

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[69] Food Chemical News, Oct. 13, 1986 at 36.

The potential harm from false or misleading claims depends on the likelihood that firms resort to such claims and consumers rely upon them. At first glance, it may appear that market forces only induce manufacturers to exaggerate and deceive. Flashy, incomplete summaries sell better than the more complicated truth, in part because audiences can't judge the accuracy of "new" information. But economic analysis and marketing research indicate, on the contrary, that market forces sometimes tend to deter potentially deceptive claims.

Most health claims for foods fall into the category of "credence claims," i.e., claims that buyers cannot verify before or after purchase.[70] Although this predicament appears to be an invitation for sellers to make misleading claims, confident that only experts will notice the problem, several factors militate against this outcome. Most consumers seem to treat unverified advertising claims with skepticism, and often take such claims as an invitation to check their truthfulness against non-partisan sources of information.[71] Confirmation can come from newspapers, magazines, or books, from physicians and other experts consulted by the consumer, from government and other public experts, from friends, and so on. Thus consumers tend to base their decisions on a portfolio of health information rather than on marketing information alone.

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[70] Darby and Karni (1973).

[71] Deighton (1983, 1984) contains illuminating discussions and empirical examination of the tendency of advertising to pose questions that are answered partly on the basis of the information from other sources. On consumer skepticism for certain kinds of claims, see Blair and Landon (1981) and Liefeld and Heslop (1985). On consumer skepticism generally, see Calfee and Ringold (1987).

Consumers also seem to rely upon market signals such as the reputation of the firm making a claim. Firms that depend upon their good names to make repeat sales are unlikely to use inaccurate claims that could devalue their reputations. Claims that are clearly refutable by health experts invite adverse publicity when the false claims become the subject of public discussion.

Another natural safeguard is the possibility of competitive advertising by firms whose products are harmed by false claims.[72] For example, ads for margarines, which have no cholesterol and are relatively low in saturated fat, have advised consumers not to be deceived by "no cholesterol" claims on substitute products with higher saturated fat content.[73] Individual incentives to undertake this task are limited, however, because other injured competitors will benefit (another version of the free-rider problem).

Even true health claims can impose substantial second-order costs. An inappropriate emphasis on a particular ingredient could lead to excessive enrichment that provides no real consumer benefit or perhaps causes more serious problems such as nutrient imbalances or toxicities. Competition that involves augmenting the health-related ingredients of foods has been referred to as a "power war" akin to the horsepower contest that arose with each new automobile model in the 1950s. Nutrition wars might lead to over-

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[72] Firms harmed by false claims by competitors can seek a resolution through two institutions. First, they can appeal to the National Advertising Division of the council of Better Business Bureaus and its appellate board, the National Advertising Review Board. They can also undertake private litigation under Section 43(a) of the Lanham Act, which allows business to sue one another for false advertising. See Mathios and Plummer (1988).

[73] See Section V(B) for an example of such a claim for Promise spread.

fortification of foods or excessive focus on some attributes to the neglect of others of equal importance.[74]

This potential problem has troubled the FDA since the beginning of nutritional labeling in the 1970s. For example, Dr. Sanford A. Miller, formerly director of the FDA's Center for Food Safety and Applied Nutrition and vocal opponent to over-fortification has reportedly stated that:

> The principal factor that must be borne in mind is that fortification of foods with specific nutrients is nonselective in that it affects all members of the population. The medical arguments against higher levels of iron fortification of enriched bread and flour in the 1970s were based on this premise and the resultant danger from increased exposure to the vulnerable subpopulation with iron overload diseases. Those arguments ultimately prevailed, and the agency suspended efforts to increase iron levels in the standard for these foods.[75]

In addition, Miller points out that many nutrients "such as vitamin A and vitamin B_6, are not as benign as some people would believe, and numerous complex interactions occur among nutrients which could upset the nutrient balance in the food supply."[76]

Over-fortification risks must be considered when evaluating possible costs of allowing health information in food labeling. But the potential danger of nutrition power wars should be compared to the alternative, which is often no competition at all on nutrition attributes. Moreover, all power races are not alike. Races to reduce the content of harmful substances like saturated fat are not accompanied by the potential over-fortification risks

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[74] For example, Sanford A. Miller, former Director of the Center for Food Safety and Applied Nutrition at the FDA, has expressed concern that "power races" resulting from health claims could lead to an over-fortification of the food supply, which could harm consumers. See Food Chemical News, Feb. 2, 1987 at 52-53 and Food Chemical News, June 22, 1987 at 44.

[75] Food Chemical News, Feb. 2, 1987 at 53.

[76] Ibid. at 53.

typically associated with power races. Because over-fortification risks are likely to vary substantially from substance to substance, it seems unlikely that the same standard should apply to all related health claims.

E. Conclusion

The economic analysis indicates that health claims are accompanied by a complex mixture of costs and benefits, which are likely to vary substantially from claim to claim. It also appears that the benefits will outweigh the costs in many cases, especially if regulatory mechanisms remain in place prohibiting claims that are clearly false. An outright ban therefore does not appear to be in the consumer interest. How should claims be regulated once the ban is lifted? Section IV addresses this question.

IV. DECISION RULES FOR REGULATING CLAIMS

A. Uncertainty and Regulatory Error

Uncertainty pervades decisions on the regulation of health claims because the body of research on diet and health is constantly changing and the nature of consumer response to information is poorly understood. Regulators face uncertainty about: (a) the extent to which a health claim is true[77]; and (b) the costs and benefits of the claim. Decisions made under these conditions are plagued by two types of regulatory errors: allowing harmful claims (Type I error) or prohibiting beneficial claims (Type II error).[78] Both can harm consumers.

There are good reasons to doubt the truthfulness of health information provided by even the most responsible manufacturers. Food marketers typically want to use recent findings on diet and health. Claims tend to

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[77] It is important to distinguish between the truth of a health claim and the truth of statements regarding the evidence in favor of the health claim. For example, the statement that "researchers at University X found that soluble fiber may help reduce serum cholesterol" can be true even though scientists do not yet know the true relationship between soluble fiber and serum cholesterol. Inaccurate statements regarding the evidence in favor of the health claim (for example, stating that the researchers are from University X when in fact they are from University Y) would be prohibited under most decision rules. The health claims debate is therefore not about when to allow inaccurate statements about health research. The debate is about when to allow accurate statements when the underlying health relationship is uncertain.

[78] In the parlance of statistical decision theory, Type I error refers to the rejection of a "null" hypothesis that turns out to be true and Type II error refers to the failure to reject a "null" hypothesis that turns out to be false. In the present case we take the null hypothesis to be that the health claim in question is, on balance, harmful. Thus a Type I error would be to allow a claim that turns out to be harmful, and a Type II error would be to prohibit a claim that turns out to be beneficial.

focus on the relatively new research connecting fiber and cancer, for example, rather than on the long established connection between vitamin D and rickets. But "new" information, by its very nature, is nearly always in doubt, and new trends in health advice, even ones embraced by reputable scientists, frequently are later found to lack scientific support. However, history has shown that many hypotheses originally considered to be unfounded have proven to be true, despite initial opposition from the medical community. For example, insulin treatment for diabetes faced strong resistance at its inception, and effective treatments for arthritis were actually abandoned and later resumed as medical science progressed.[79] More recently, the FDA has announced that it may be time to overturn its ban on cyclamate. Many experts now believe that cyclamate, which was once thought to cause bladder cancer and birth defects, is harmless. In fact, some experts argue that evidence of harm from cyclamate was never very convincing.[80]

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[79] Hutt (1986 at 24) notes that insulin was opposed by 90 percent of the medical profession when it was first introduced. Goodwin and Goodwin (1984) identify efficacious therapies that were ignored or rejected for a time (despite their effectiveness) because their presumed mode of action contradicted the prevailing medical theories. Two examples are the use of colchicum for gout and high dosage aspirin for arthritis.

[80] The Washington Post, May 16, 1989 at A1 and A7 and May 17, 1989 at A6.

Thus scientific conclusions about diet and health tend to be tenuous.[81] Surprisingly, even many of the "consensus" scientific conclusions currently presented by public health advocates and the media are, in fact, still clouded by uncertainty. A recent attack was levied against the consensus agreement on the relationship among dietary cholesterol, saturated fat, and heart disease.[82] Moreover, even when there is wide agreement upon a central core of knowledge, uncertainty remains about fundamental details. Despite substantial agreement that consumption of saturated fat raises serum cholesterol, for example, many would argue that this relationship does not hold for all types of saturated fat.[83] The "average" effect of fat consumption on coronary heart disease in large populations may be clear, but effects among sub-populations and on individuals may be in doubt. In

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[81] The lack of "absolute proof" about diet and health relationships is discussed in NRC (National Research Council) (1989) at 28-1. The report notes that "although much remains to be learned before firm conclusions and recommendations can be made regarding the total impact of diet on chronic disease risk . . . it would be derelict to ignore the large body of evidence while waiting for absolute proof of benefit from dietary change." Chapter 28 of the report is fascinating because it shows that the committee weighed essentially the same factors balanced under an expected value rule (in the terminology of the report, "the level of certainty, the potential for public health benefit, and the likelihood of minimal risk") to determine what to recommend and how precisely to phrase its recommendations. More specifically, the committee notes that "the strength of the evidence might not be the only relevant criterion for determining the course of action."

[82] See Thomas J. Moore's critique of the process used to achieve consensus on the relationship between diet, serum cholesterol, and heart disease. Moore argues that because of flaws in the consensus making process, an official consensus is a very poor proxy for the truth. (The Atlantic Monthly, September 1989 at 37-70.)

[83] Bonamone and Grundy find that stearic acid (one type of saturated fatty acid) appears to be as effective as oleic acid (one type of monounsaturated fatty acid) in reducing serum cholesterol when either replaces palmitic acid (another type of saturated fatty acid) in the diet. (Bonamone and Grundy (1988) at 1244.) A lively discussion of some controversial aspects of this finding can be found in letters to the editor of The New England J. of Medicine, October 20, 1988 at 1089-1091.

addition, short-term effects may differ to an unknown degree from long-term effects. Finally, the existence of an effect may be well established, but its magnitude may be unknown.[84]

The second area of uncertainty, which would remain even after the question of scientific truth is "established," is how to measure the net benefit of true claims and the net cost of false claims. Uncertainty about the effect of both true and false claims is compounded by several unknown factors related to consumer and firm behavior. For example,

> A marketing claim about fiber and cancer may or may not accurately change consumer views on the fiber-cancer connection;
>
> A change in consumer knowledge may or may not change consumption of the advertised brand or general product class;
>
> The claim may or may not trigger changes in product quality;
>
> Consumers may or may not learn that a claim is false, thus raising suspicions of other claims, even true ones, and diminishing the power of nutrition education efforts.

Of the many uncertain factors affecting policy toward health claims, one has dominated policy debates: the level of substantiation that should be required for a claim. Recent discussion has revealed two schools, one that would adjust the required level of substantiation to take into account the mix of costs and benefits associated with specific claims and one that

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[84] See "Specificity in Dietary Guidelines Tied to Health Claim Problems," Food Chemical News, Oct. 6, 1986 at 15. The American Medical Association has specifically opposed quantitative advice on fiber intake or on other dietary matters. The Director of Personal and Public Health Policy for the AMA recently questioned the "wisdom" of recommending dietary changes for healthy persons. (Food Chemical News, March 31, 1986 at 24, 25.) He specifically opposed quantifying dietary targets for fat, sodium and fiber, etc. The NRC (1989) explains how it decides when to quantify dietary advice and when to keep its recommendations more general. The decision is based on a weighing of the costs and benefits of both approaches in light of the degree of certainty about the relevant diet/disease relationships.

advocates requiring a fixed level of substantiation (approximately a "consensus" among scientists). These two approaches are described and compared in the next two sections.

B. The "Expected Value" or "Flexible Substantiation" Rule

If the net results of allowing health claims for foods were known with certainty, regulators could simply ban health claims that do more harm than good and allow claims that result in more good than harm. Unfortunately, in the face of uncertainty, regulators cannot always distinguish one group from the other. One way to estimate which group a claim belongs to is to conduct an expected value analysis. The corresponding expected value rule balances estimated costs against estimated benefits and takes uncertainty about the ultimate truthfulness of a claim into account.

The expected value approach does not assume that uncertainty can be reduced to a precise set of probabilities and numerical estimates of costs and benefits. Rather, the rule acknowledges that mistakes can be made, and it attempts to minimize the expected costs of Type I and Type II regulatory errors. More specifically, the expected value approach incorporates uncertainty into a cost/benefit analysis framework by weighing the likely harm from both types of regulatory errors.[85]

Application of this rule begins with the best available estimates of costs, benefits, and associated probabilities:

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[85] The simple analysis described here considers only the decision to allow or prohibit a claim given the available evidence. A more complicated expected value framework could be devised whereby the cost of obtaining additional substantiation is considered explicitly to determine what level of substantiation would be required for a continuum of claims.

EB = Expected benefit of allowing the claim,

= $P_t B_t$,

EC = Expected cost of allowing the claim,

= $P_f C_f$, and

EV = Expected Value of Allowing Health Claim

= EB - EC,

= $P_t B_t - P_f C_f$,

where

P_t = probability that the claim will turn out to be true,

P_f = probability that the claim will turn out to be false

= $(1 - P_t)$,

B_t = estimated net benefit[86] of allowing the claim if it turns out to be true (or, equivalently, the estimated net cost of prohibiting the claim if it proves to be true), and

C_f = estimated net cost of allowing the claim if it turns out to be false (or, equivalently, the estimated net benefit of prohibiting the claim if it proves to be false).

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[86] The net benefit of allowing a claim that turns out to be true is the benefit of allowing a claim that turns out to be true minus the cost of allowing a claim that turns out to be true. Likewise, the net cost of allowing a claim that turns out to be false is the cost of allowing a claim that turns out to be false minus the benefit of allowing a claim that turns out to be false. Net amounts are used to account for the possibility that a claim about a relationship that turns out to be true can impose costs. (For example, costs are incurred if a true claim induces people to forgo treatment for serious illness.) Similarly, even claims that turn out to be false can be beneficial if they increase awareness about a potential problem. Under the terminology used here, allowing claims that turn out to be true is assumed to yield net benefits. Likewise, allowing claims that turn out to be false is assumed to yield net costs.

The "expected value rule" for regulation is as follows:

Prohibit the claim if the expected costs outweigh the expected benefits of allowing the claim, i.e., if EC > EB.[87]

This is equivalent to comparing the likely outcome of prohibiting a claim to the likely outcome of allowing the claim and choosing the action that is likely to benefit society the most.

The rule clearly weighs potential harm from both Type I and Type II regulatory errors.[88] This approach has been extensively discussed in the literature on FTC advertising regulation as well as in many other places, such as the analysis of fact-finding in litigation.[89] A critical characteristic of the expected value approach is that there is no fixed relationship between P_t, the probability the claim is true, and the decision to prohibit the claim. A claim with great potential benefits and small potential costs would have a positive net expected value even if the probability of truth were not large. A theoretical example would be a claim that reducing dietary cholesterol may reduce the likelihood of heart disease, when the relationship between cholesterol and heart disease is less than fully established. In this case the potential cost to health of reducing dietary cholesterol is low because there

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[87] If it turned out that EC > EB for almost all health claims, then a ban on health claims might be an optimal policy.

[88] This rule outlined here does not take into account risk-aversion, that is, the willingness of most persons to pay a premium in order to replace a risky situation with a more certain one. Stokey and Zeckhauser (1978) explain how policy makers can modify an expected value rule to account for risk aversion. Nor does the rule deal with distributional issues.

[89] Eighmey (1978), for example, proposed the expected value rule as a way for the FTC to determine the adequacy of substantiation for advertising claims. Eighmey cites precedents for his approach, noting the work of Mittelstaedt and Nils-Erik (1975) on advertising substantiation and that of Kaplan (1968) on legal fact-finding. For more on an expected value approach, see Stokey and Zeckhauser (1978) at 201-254.

is little evidence that people should consume minimum levels of dietary cholesterol to maintain good health.[90]

C. Consensus Rules: Fixed and Flexible

Alternatively, a regulator can use a consensus rule. The consensus rule for decision making under uncertainty can be stated in the following way:

> **Prohibit a claim unless a consensus of scientific experts agree that the underlying relationship exists.**

This rule requires a method for determining when a "consensus" has been formed.

Typically, a consensus does not require unanimity, but does require that the vast majority of recognized experts judge a claim to be true.[91] Assuming that the degree of consensus is positively related to the probability that a claim is true, and employing the notation defined above, a fixed consensus rule can be stated as follows:

> **Prohibit claims unless P_t (the probability that a claim is true) is greater than some baseline probability level P_0, where P_0 is "close" to one, for example, .95 or .99.**

The fixed consensus rule requires a high probability of truth for all claims *uniformly*, without taking into consideration how the potential

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[90] See NRC (1989) at 7-108. According to the report, "there is no experimental or observational evidence to support the concept that cholesterol is an essential nutrient." Although there have been no experimental tests on the effects of cholesterol deprivation on children or growing animals, such tests are thought to be non-existent because "the hypothesis is considered to be very unlikely."

[91] One point we shall ignore is the possibility that scientists may reach a consensus on whether to offer certain advice even when a consensus does not exist on the medical effects involved. For example, scientists could agree on advising middle aged people to exercise moderately, even in the absence of definitive evidence on the medical advantages of moderate exercise.

benefits from true claims compare to the potential costs from false ones. This approach obviously protects consumers against potential harm from claims that prove to be false. But it carries a higher risk of harm from prohibiting claims that eventually prove to be true -- claims that might have benefited consumers. In the terms of statistical decision theory, the rule assumes the costs of a Type I error (allowing a claim that proves to be false) are far greater than the costs of a Type II error (prohibiting a claim that proves to be true). Sometimes this is true; but when it is not, application of the fixed consensus rule would harm consumers.[92]

Although a consensus requirement generally brings to mind a fixed consensus rule, this is not the only way to employ a consensus approach. In fact, the approach can also be used to generate a "flexible consensus" rule that is equivalent to the expected value rule. Under this rule, the required level of consensus is permitted to vary according to the likely costs and benefits of allowing a claim. The two rules will work the same if the required probability of truth (P_0) is that probability necessary to make the expected value of allowing a claim positive. A claim would be allowed when the actual level of consensus is greater than this level.[93] This "flexible consensus" approach can be formulated by setting EV equal to zero and solving for P_t^*:

$$EV = 0 = P_t B_t - (1-P_t)C_f$$

hence

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[92] If it could be shown that, on average, the cost of Type I error exceeds the cost of Type II error then a consensus approach would be preferred. This seems unlikely to be the case for foods, which are already a safe part of the food supply.

[93] See Eighmey (1978).

$$P_t^* = C_f/(B_t+C_f)$$

$$= 1/(B_t/C_f + 1)$$

The flexible consensus rule can therefore be stated as:

Allow claims when the probability that a claim is true exceeds P_t^*.

Thus, it is the *uniformity* of a fixed consensus approach, not the requirement of a given level of consensus, per se, that distinguishes it from the expected value approach.

When the framework is viewed this way, it is easy to see that in many cases the probability of truth does not have to be nearly as high as .95 to make it beneficial to allow a claim. More specifically, the above equation shows that if the likely benefits of allowing a claim if it turns out to be true equals the likely costs of allowing a claim if it turns out to be false ($B_t = C_f$), then there only has to be slightly more than a 50:50 chance that a claim is true ($P_t>.5$) to make it beneficial to allow the claim.[94]

D. Harm from Type II Regulatory Error

Harm from claims that are allowed is identified more easily than harm from the lack of information that the public never sees. Thus it is understandable that those who support a fixed consensus rule emphasize the importance of minimizing Type I regulatory error (minimizing claims that

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[94] The same probability of truth level is required when the analysis is phrased somewhat differently. One can think of the problem as balancing the disutility of allowing a claim that proves to be false against the disutility of prohibiting a claim that proves to be true. This is the method used by Kaplan, where he weighs the disutility of acquitting a guilty man (Type I error, when the null hypothesis is that the defendant is not guilty) against the disutility of convicting an innocent man (Type II error). Kaplan (1968) at 1071-1072.

prove to be false). But there is no reason to assume that Type II errors are less important.

The history of federal cholesterol labeling regulations illustrates that Type II regulatory errors can also be serious.[95] Research conducted during the 1950s indicated a relationship between serum cholesterol levels and heart disease, and suggested that saturated fat intake tends to increase serum cholesterol while polyunsaturated fat intake tends to decrease serum cholesterol. Manufacturers reacted to these findings by adding cholesterol information to labels of certain foods. In 1959 the FDA responded by announcing that

> . . . the advisability of making extensive changes in the nature of dietary fat intake had not been demonstrated, and that any labeling claim related to heart disease would be regarded as illegal.[96]

On these grounds the FDA not only prohibited explicit claims relating cholesterol and health, but even banned use of the word cholesterol on labels.[97] CPC/Best Foods reportedly discontinued consumer advertisements for Mazola

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[95] This section relies on Hutt (1986). For more on the history of the science and politics of various government decisions pertaining to the diet heart disease hypothesis see Levine (1986) and Hausman (1981).

[96] 24 Fed. Reg. 9990 (1959). It is not clear what prompted this statement. Two reasons that have been suggested are (1) early advertising campaigns by oil and margarine companies and (2) fears of future label claims. See Levine (1986) at 58.

[97] A striking parallel occurred at the same time as the cholesterol labeling controversy. In 1957 some leading cancer experts recommended that smokers switch to lower tar cigarettes The market responded by advertising tar content and introducing effective filters. Because the FDA has no jurisdiction over cigarettes, only the FTC could deal with this development. In 1960 the FTC decisively intervened to halt tar and nicotine advertising. The FTC's reasoning at the time, like that of the FDA, appeared to be that only claims supported by a consensus should be tolerated. And a consensus had not formed on the benefits of lower tar and nicotine cigarettes. See Calfee (1985) and (1986).

oil that had included clippings from newspaper articles describing scientific research on polyunsaturates and heart attack risks in response to the 1959 FDA statement.[98] Reports in the trade press indicated a belief among marketers that the FTC would be cooperating with the FDA and that it shared the FDA's position on cholesterol claims.[99]

By January 1961, the American Heart Association (AHA) advised that consumers might be able to decrease the risk of heart attack by controlling their fat consumption under medical supervision.[100] Moreover, the AHA recommended that food labels provide explicit information on fat composition.[101] The FDA rejected this approach and stated in 1964 that:

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[98] Levine (1986) at 61. Levine further reports that

> CPC staff interpreted the regulations to mean that the company could not directly link polyunsaturates to preventing heart disease--but it could describe the polyunsaturated nature of the product without mentioning why people should care about polyunsaturates [emphasis in original].

In addition, Levine suggests that some manufacturers continued to make similar claims to consumers.

[99] Cooperation between the FDA and FTC on cholesterol claims was reported in Printer's Ink. According to the publication,

> the FTC is poised to move against the advertisers of anti-cholesterol products if the FDA action doesn't achieve broad results . . . if advertisers don't alter their advertising as well as their label and point-of-sale claims, it is understood that the FTC will move in.

(Printer's Ink, December 18 1959 at 13.) A few years later, an advertising executive concluded that an FTC ruling against Kraft Foods Co. (a client of his ad agency) forbid the firm from using the word cholesterol in ads for synthetic eggs because "the term implies a health benefit that hasn't been established (by the FTC)." (Advertising Age, February 3, 1964 at 86.) This interpretation of the FTC's actions reflects a belief that the FTC was using a rationale for limiting cholesterol information similar to the FDA's.

[100] Cited in Hutt at 30, from The American Heart Association Ad Hoc Committee on Dietary Fat and Atherosclerosis, "Dietary Fat and its Relation to Heart Attacks and Strokes," 23 Circulation 133, 134 (Jan. 1961).

[101] Ibid. at 31.

> [L]egal action will be taken if vegetable oil products continue to be misbranded with claims that they are "poly-unsaturated" and thus supposedly effective in treating or preventing heart or artery disease.[102]

In the same year Hutt reports that the "FDA seized Nabisco Shredded Wheat because the back panel of the package discussed the relationship between serum cholesterol and heart disease."[103]

Enforcement activity dwindled during the early 1970s as further evidence in support of the diet-heart disease hypothesis emerged. By 1973 cholesterol and fatty acid labeling became an optional part of the FDA's nutritional labeling program. Nonetheless, prohibitions on specific health claims -- claims indicating, suggesting or implying that a product will prevent, mitigate, or cure heart or artery disease -- remained on the books.[104] Revised cholesterol labeling definitions were proposed by the FDA in 1986 and are currently under review.[105]

The FDA's actions during these years suggest that it focused almost exclusively on the possibility that the new propositions about cholesterol and

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[102] Cited in Hutt at 31. From FDA Press Release HEW-B35 (May 27, 1964).

[103] Cited in Hutt at 34, FDA Foods Notice of Judgement No. 29,850 (May 1965). Hutt further notes that the case went by default because the company had discontinued its use of the package a month earlier. The agency reportedly believed that even if a link between lower cholesterol and heart disease were "unquestionably" proven, information on diet and heart disease would constitute false health claims because there was no way to insure that the public would make the proper dietary changes. (Wall Street Journal, September 28, 1964 at 8.) The philosophy therefore appears to have been that nutrition and health information should stay out of labeling because it was too complicated for most consumers. Some commentators have argued that the consumers who were supposedly misinformed were, in fact, quite aware of the latest medical research. See Hausman (1981) at 151 and Food Chemical News June 15, 1964 at 8.

[104] Cited in Hutt at 38. From 21 C.F.R. Sec. 101.25(g) (1985).

[105] See 51 Fed. Reg. at 42,584-42,593.

health would prove to be false (preventing Type I error).[106] Justification for the ban relied mainly on the lack of proven benefits, rather than on potential risks.[107]

The forgone potential benefits in this episode were probably large. If the FDA had permitted cholesterol and fatty acid labeling sooner, the result would almost certainly have been greater cholesterol awareness and more rapid dietary improvements during the 1950s and 1960s.[108] On the other hand, the potential health cost of allowing cholesterol labeling seems small.[109] Moreover, despite various concerns about the possible costs of reducing saturated fat, dietary cholesterol, and serum cholesterol, the policy debate against allowing cholesterol information has not focused on evidence of such effects, but rather on the fact that a relationship between diet and heart disease had not been "proven".

The cholesterol example is admittedly but one "worst case" example from FDA history, which also includes many decisions that turned out better. Nonetheless, the example does illustrate that Type II regulatory errors can

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[106] See Milstead (1963) for a vivid description of the FDA's view that claims such as "less cholesterol" and "not hydrogenated" misled consumers because they were based on a "theory" that was "unproved."

[107] The FDA may have been concerned about diluting the credibility of future claims by allowing claims without strong support. Although this is an important potential cost to consider, it can be avoided more appropriately by requiring manufacturers to disclose the basis for their claims.

[108] The extent to which the FDA's policy statements and enforcement activity affected marketing practices is unclear. There is evidence to suggest that some manufacturers did not comply with the FDA. For example, see Food Chemical News June 15, 1964 at 8-9 and Levine (1986) at 61. A content analysis of past advertising and labeling claims related to the diet-heart disease hypothesis would be a useful addition to the health claims literature.

[109] See Section V(A) for a more complete discussion of the costs and benefits of saturated fat and dietary cholesterol reductions.

be costly and that any regulation to determine which health claims to allow should explicitly weigh the costs of Type II error against the cost of Type I error.

E. Conclusion

Decision rules are tools for repeated use. Over the long run, errors will inevitably be made using any rule. When assessing the pros and cons of different rules, the balance among various errors over time must be considered. The expected value rule seeks to estimate both Type I and Type II errors and to minimize the sum. On the other hand, the fixed consensus rule contains a strong bias toward minimizing Type I error and maintaining the status quo.[110] It reduces the risk of false claims but increases the costs due to delays in the delivery of health information. The expected value approach is likely to generate more benefits in the long-run because it avoids prematurely emphasizing Type I errors and there is little evidence that Type I errors are more costly than Type II errors for health claims about mainstream foods.

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[110] In fact, some analysts have argued that it was the government's desire generally to maintain the status quo and not to "rock the boat" that prevented it from responding to accumulating evidence on diet and heart disease years earlier. See Hausman (1981), especially the chapter entitled "The Federal Turtle" at 148-175.

V. IMPLEMENTING AN EXPECTED VALUE RULE

In principle, an expected value or flexible substantiation rule is preferable to a fixed consensus rule for the reasons outlined in the previous section. One might now ask: "But can the expected value principle work in practice?" Examples of the application of the expected value approach at the FTC and examples of how the principles might be applied to claims about saturated fat and heart disease indicate that the approach can be used to regulate health claims.

A. FTC Policy and the Expected Value Rule

FTC regulators rely primarily on what is, in effect, an expected value approach for making advertising substantiation decisions. This doctrine has evolved through FTC case law since 1972[111] and was explained in a 1984 policy statement.[112]

The FTC's ad substantiation doctrine requires advertisers and ad agencies to have a "reasonable basis" for advertising claims before they are made. The level of evidence required depends partly upon the level of support indicated by the advertising. When a claim expressly indicates or reasonably implies a particular level of support, the FTC expects the firm to have, at a minimum, the advertised level of substantiation. For example, if an advertiser claims that "a majority of doctors believe that saturated fat

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[111] See Thompson, 104 F.T.C. at 813, citing Pfizer, Inc., 81 F.T.C. 23 (1972).

[112] See Thompson, 104 F.T.C. at 839-42. Also see Ford and Calfee (1986) for the events leading to the advertising substantiation statement.

consumption is related to heart disease," the firm must show that a majority of doctors believe this to be true.

When a given level of substantiation is not clearly expressed or implied by a claim, the FTC requires the firm to provide data documenting a "reasonable basis" for the claim. In deciding whether substantiation is "reasonable," the Commission weighs six factors that relate to the expected costs and benefits of allowing a claim:

(1) the type of claim;

(2) the product;

(3) the consequences of a false claim;

(4) the benefits of a truthful claim;

(5) the cost of developing substantiation for the claim; and

(6) the amount of substantiation experts in the field believe is reasonable.

These factors correspond roughly to the variables that are estimated and balanced under the expected value rule defined in the previous section. In assessing the first two of these factors (type of claim and product), the FTC considers whether the product raises health, safety, or other special concerns and whether the claims at issue are specific or general, or capable of evaluation by consumers.[113] The third, fourth, and fifth factors (the benefits if the claim is true, the consequences of a false claim, and the cost of additional substantiation) are often examined simultaneously. They help to determine whether requiring a particular level of substantiation is likely to harm consumers by preventing the dissemination of potentially valuable

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[113] Thompson, 104 F.T.C. at 822-23.

information.[114] The sixth factor (expert judgment and standards) relates to the probability that a particular claim is true.

Thus the FTC approach focuses on the likely consequences of both allowing or prohibiting a claim. The six factors can be analyzed without placing an undue emphasis on either type of regulatory error, allowing false claims or prohibiting true claims.

The reasonable basis approach has frequently been used to prohibit health claims thought by the FTC to be harmful. For example, in 1983 the FTC secured a consent agreement against Estee, Inc. regarding its advertising for cookies and other foods sold primarily to diabetics. The FTC charged, among other things, that the company lacked a reasonable basis for its health claims about the effect of its products on blood sugar levels. The consent order requires that Estee have "competent and reliable scientific evidence" to support claims that a food affects blood sugar levels and that certain foods have a particular health-related quality for diabetics.[115] A noteworthy aspect of the FTC order is that it requires future claims to be backed by evidence "of the type and quantum appropriate for the representation made."[116] The level of substantiation required of Estee is therefore flexible in that it depends upon the mix of costs and benefits associated with a particular claim. The level of scientific support for a carefully qualified claim is lower than for a more general claim without the same caveats.

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[114] Thompson, 104 F.T.C. at 823.

[115] Estee Corp., 102 F.T.C. 1804,1811 (1983).

[116] Ibid. at 1811.

More recently, the FTC charged Campbell Soup Co. with failing to disclose the sodium content of its soups.[117] According to the administrative complaint, Campbell represented in its ads that it had substantiation for the claim that most of its soups make a positive contribution to a diet that reduces the risk of heart disease. However, the complaint charged that Campbell did not have substantiation for its claims, and the representation that it did was therefore false, misleading, or deceptive. If the Commission finds that Campbell violated the law, it may order the company to notify consumers of the sodium content of its soups in certain advertisements. The order may also prohibit Campbell from advertising that its products can contribute to a diet that reduces the risk of heart disease, unless it has substantiation for its claims.

The FTC has also used the reasonable basis approach to encourage the dissemination of beneficial information. For example, as noted earlier, Carol Crawford, then director of the FTC's Bureau of Consumer Protection, supported Kellogg's use of the NCI's recommendations on fiber and cancer in its All-Bran advertisements.[118] Crawford found that Kellogg accurately represented the nature of the evidence supporting its health claims. Moreover, she emphasized that the ads presented information that would be strongly beneficial to consumers if it turned out to be true, but posed modest harm if it turned out to be false.

The FTC's advertising substantiation doctrine, which explicitly varies the required level of substantiation according to potential costs and benefits, strongly resembles an expected value rule. Thus FTC experience suggests

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[117] FTC News, January 26, 1989.

[118] Crawford (1984).

that a policy oriented toward balancing costs and benefits of health claims is feasible.

B. Example: Evaluating Claims about Fat, Cholesterol, and Heart Disease

Although a complete cost/benefit analysis of any health claim is beyond the scope of this paper,[119] we sketch out how a regulator might structure an expected value analysis of marketing claims linking saturated fat to coronary heart disease (CHD) based on data available today. We then consider whether a regulator could have conducted a similar analysis twenty-five or thirty years ago, when the science was less certain. The example illustrates that although data are typically insufficient to estimate probabilities, costs, and benefits precisely, it is possible to improve decision making by obtaining rough estimates of these variables.

The Claim

A four page ad for Promise spread in USA Today[120] provides examples of recent health claims. The ad explains how saturated fat content and dietary cholesterol are thought to be related to serum cholesterol and the risk of CHD. It also tells readers where to send for further information and explains that Promise spread, in contrast to butter, contains no cholesterol and is relatively low in saturated fat. Among other recommendations, the ad suggests that consumers "Eat a variety of foods, concentrating on those that

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[119] We do not claim to have any particular medical expertise on the relationship between various fats, serum cholesterol, and heart disease. The models sketched here were built upon a brief review of the literature and are meant only to be illustrative. Further refinements could undoubtedly be made by medical researchers and such improvements would only enhance our point, which is that medical evidence and consumer research can be used to estimate the effects of allowing various claims.

[120] USA Today, May 6, 1987 at 5A-8A.

are low in fat and cholesterol." With regard to the consumption of butter and margarine, the ad recommends the following:

> When buying margarine, look for brands that list liquid oils first among the ingredients, rather than hydrogenated or partially hydrogenated oils. In addition to checking the ingredients, also check the nutrition label for the amount of fat. Go easy on butter, which contains cholesterol as well as saturated animal fat. But be aware that while margarines contain no cholesterol, some can be almost as high as butter in saturated fat content. Again watch for products that say "no cholesterol," and check them for saturated fat.

As explained below, this claim would undoubtedly pass muster under an expected value test today. The information appears to be consistent with the dietary recommendations currently touted by many scientific organizations. Moreover, there is a broad consensus among expert organizations that changes in diet can significantly reduce the incidence of CHD and that the health costs of dietary changes, if the diet heart-disease hypothesis turns out to be wrong, are probably small.

How would similar claims have stacked up under an expected value rule twenty-five or thirty years ago, when they were being prohibited by the FDA and the science was less certain? We cannot tell for sure. It is possible that an expected value analysis would have led to a decision to ban health claims. But, as described below, there is a good chance that the agency's decisions would have been quite different.

A Rough Expected Value Analysis Today

The expected value of allowing health claims like those made for Promise will depend upon predictions of how the information changes behavior. In general, benefits are likely to accrue if consumers switch from foods higher in saturated fat and cholesterol, or from more expensive products of equal nutritive value. Costs are incurred if the advertisement

induces people to switch away from more beneficial or less expensive products. Therefore, the critical information that requires quantitative estimates are (a) the health effects of reducing dietary cholesterol, saturated fat, and serum cholesterol and (b) the relative cost of the substitute products. Trade-offs in taste and texture also merit consideration. In addition, when deciding whether a claim should be prohibited, one must consider not only the effect of the ad or label in question, but also the effect of the prohibition on claims by other manufacturers of different products. Agency action signaling that a claim is impermissible can deter many other firms from spreading similar information through marketing.

To estimate the likely health effects of allowing manufacturers to recommend that consumers select products that are relatively low in saturated fat,[121] a policy analyst is likely to turn to the National Research Council's report Diet and Health: Implications for Chronic Disease Risk (hereafter, NRC report) for guidance[122]. This is a particularly useful source because it includes what is essentially a cost/benefit analysis of the NRC's dietary recommendations. This analysis provides a guide for a policy maker who needs to make decisions concerning which claims about saturated fat, dietary cholesterol, and heart disease to allow.

The NRC report suggests that the "Keys" equation can be used to estimate the effects of changes in saturated fat and cholesterol consumption

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[121] For illustrative purposes, we limit our analysis to the claim to choose products relatively low in saturated fat. An expanded analysis could include the effects of urging dietary cholesterol reductions, as well.

[122] NRC (1989, Pre-Publication copy).

on serum cholesterol.[123] This equation served as the basis for the NRC's estimates of the serum cholesterol reductions that would occur if consumers adhered to its dietary recommendations. More specifically, it was estimated that a 4% reduction in calories from saturated fatty acids[124] and a reduction in dietary cholesterol from 420 to 300 mg daily[125] may lead to a 20 mg/dl (or 10%) reduction in mean serum cholesterol levels.[126]

The NRC then linked the estimated changes in serum cholesterol resulting from adherence to its dietary recommendations to changes in CHD risk. It was estimated that at least a 10% reduction in serum cholesterol levels "should lead to at least a 20% reduction in CHD risk in the United states beyond 1987 levels."[127] In other words, a 1% reduction in serum

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[123] The Keys equation, which estimates the effect of saturated fat, polyunsaturated fat, and dietary cholesterol on serum cholesterol is widely cited. Grundy (1986) uses it to describe what is known about the relationship between saturated fat and serum cholesterol. The equation is also cited in The Surgeon General's Report on Nutrition and Health. (U.S. Public Health Service (1988) at 97. The equation predicts that a 1% increase in caloric intake contributed by saturated fat will increase serum cholesterol by approximately 2.7 mg/dl. It also predicts that a one unit increase in the square root of daily dietary cholesterol in mg/1,000 calories will lead approximately to a 1.52 mg/dl increase in serum cholesterol.

[124] This is a reduction from 14 to 10% of calories with no change in polyunsaturated fat intake.

[125] This is a reduction of 120 mg, or 40 mg/1,000 kcal (assuming an intake of 3,000 calories per day). NRC (1989) at 28-49.

[126] NRC (1989) at 28-47 and 28-48. The same estimate is derived by applying the results of Keys (1965), which as noted above is also reported in The Surgeon General's Report on Nutrition and Health (1988). The part of the reduction due to the decrease in saturated fat, as estimated using the Keys equation, is 10.8 mg/dl (4 x 2.7). The part of the reduction due to the decrease in dietary cholesterol is approximately 9.5 mg/dl (1.5 x sq.rt. 40 = 1.5 x 6.32 = 9.5). And 10.8 mg/dl + 9.5 mg/dl = 20.3 mg/dl (or roughly 20 mg/dl, the NRC's estimate). Given that the mean serum cholesterol level is estimated to be approximately 210 mg/dl, this 20 mg/dl reduction translates into approximately a 10% reduction in serum cholesterol.

[127] Ibid. at 28-54.

cholesterol leads roughly to a 2% reduction in CHD risk.[128] This estimate was based upon the NRC's review of all of the evidence, not upon a single definitive study.

Possible costs of making the recommended reductions in saturated fat and dietary cholesterol are also considered in the report. The NRC concluded that it "found no evidence to suggest that the recommended reduction in SFA (saturated fatty acid) intake will increase the risk of any other chronic disease."[129]

Of course, when recommending reductions in saturated fat, one has to consider the effects of likely substitutions. With regard to possible resulting increases in monounsaturated fatty acid intake the NRC concludes that "Evidence within populations is not strong but suggests that substitution of MUFAs (monounsaturated fatty acids) for SFAs may decrease cancer risk." The NRC does not recommend increasing polyunsaturated fat intake. Animal studies indicate an increase in colon or mammary cancers at very high polyunsaturated fat intake. However, substitutions of up to 10% of calories from saturated fats to polyunsaturated fats appears not to increase the population risk of cancer. Moreover, few populations regularly consume more than 10% of calories from polyunsaturated fats, and it appears that Americans fall well below this average.[130]

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[128] The Surgeon General notes that dietary intervention trials have demonstrated that each 1% reduction in total blood cholesterol is accompanied by about a 1.5% reduction in heart disease risk. (U.S. Public Health Service (1988) at 121.)

[129] Ibid. at 28-42.

[130] NRC (1989) at 3-27. The best available national consumption estimates indicate that American women consume only 7.4% of total calories from polyunsaturated fat. In 1985 it was estimated that linoleic acid (a primary (continued...)

Overall, the NRC found that "among dietary factors, modifications in the intake of total fat, SFAs, and dietary cholesterol are likely to have the greatest impact."[131] Moreover, in weighing competing risks involving changes in total fat, saturated fat, and dietary cholesterol, the NRC assessed the

> effect of reducing serum total cholesterol in the population on the risk of hemorrhagic stroke in hypertensives, the possible adverse effects of increased PUFA or MUFA intake, increased carbohydrate intake, increased intake of vegetables and carotene, possible increased exposure to pesticides, moderate alcohol intake versus avoidance, and the potential for nutrient deficiency or toxicity among population subgroups. Using worst-case scenarios, the committee concluded that the potential for adverse effects (e.g., increased colon cancer risk due to a reduction in the population mean for serum total cholesterol) is minimal at best and is far outweighed by the many potential benefits."[132]

After reviewing this literature, which clearly shows that the expected value of promoting reductions in saturated fat, total fat, and dietary cholesterol is likely to be positive, a policy maker using the expected value rule would look at the health claim in the context of the total message. A claim used in the context of a message urging substitution away from foods high in saturated fats towards foods lower in saturated fats would produce more benefits than the same claim imbedded in a message urging substitution in the opposite direction. Ideally, one would employ the results of marketing research to estimate the effect of a message on consumer behavior. However, such research is beyond the scope of the paper and

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[130] (...continued)
source of polyunsaturated fatty acid) accounted for only 7% of the available food supply. NRC (1989) at 3-21.

[131] Ibid. at 28-55.

[132] Ibid. at 28-52.

instead, for illustrative purposes, we will rely on some assumptions about the possible response to get an idea of the magnitude of likely effects.

Our example is based upon the following assumptions:

Daily Calories[133]	2500
Average Daily Butter Serving[134]	6.09 grams
Saturated Fat Content of Butter[135]	50.5%
Saturated Fat Content of Promise[136]	14%

For purposes of illustration it is assumed that those who respond to the ads substitute Promise for butter half of the time.[137]

Based upon these assumptions, it is estimated that daily saturated fat consumption would decrease by 1.11 grams, or 9.99 calories.[138] This is about

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[133] Approximate daily caloric intake for males aged 23-34. USDA (1984) at 154. Based on the USDA data this is a relatively high caloric intake assumption. It is much lower, however, than the 3,000 calories per day assumption used by the NRC to assess the impact of its dietary recommendations. NRC (1989) at 28-49.

[134] The per capita butter consumption was estimated to be 4.9 lbs. per year in 1985. USDA (1987) at 18.

[135] USDA (1979) at 16.

[136] This percentage was calculated using information on a Promise label. The same cost/benefit framework could be applied to more refined estimates of fatty acid content.

[137] A more complete analysis would use many different assumptions and could employ marketing researchers to estimate the effect more precisely.

[138] Half the 6.09 gram daily average butter consumption (with 50.5% saturated fat) would be replaced by Promise (with 14% saturated fat):

(3.05 grams per day)(.505 -.14) = 1.11 grams saturated fat per day.

1 gram of fat equals 9 calories.

.40% of total daily caloric intake.[139] The "Keys Equation" predicts that a .40% decrease in caloric intake contributed by saturated fat will decrease serum cholesterol by approximately 1.08 mg/dL, or about .50%.[140] Switching from butter to Promise half of the time therefore reduces serum cholesterol by approximately .50%.[141] Using the NRC's estimate that a 10% decrease in serum cholesterol is roughly related to a 20% decrease in CHD risk, we estimate that a .50% decrease in serum cholesterol would reduce CHD risk by approximately 1%.

Changes induced by health claims also affect consumers' out-of-pocket costs. If a health claim encourages consumers to pay significantly more for a product without any real health benefits, then this cost must also be considered in the analysis. But consumers realize savings, rather than costs, when switching from butter to Promise, because butter is roughly twice as expensive. On the other hand, Promise does tend to cost more than many other margarines, but Promise contains less saturated fat than many margarines. Thus net out-of-pocket costs from these health claims are probably negligible and are dwarfed in comparison to the health effects.

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[139] 1.11 g/day x 9cal/g = 9.99cal/day or .40% of total daily calorie intake (9.99cal/day / 2500 cal/day = .0040).

[140] As described earlier, the Keys equation predicts that a 1% decrease in caloric intake contributed by saturated fat will decrease serum cholesterol by approximately 2.7 mg/dL. The increase in serum cholesterol from switching to butter is thus 2.7 mg/dL x .40 = 1.08 mg/dL. The percentage change is estimated by employing the fact that the average serum cholesterol level for Americans is estimated to be about 210 mg/dL. NRC (1989) at 28-48. Thus the percentage is estimated as: 1.08 mg/dL / 210 mg/dL = .005.

[141] One could further refine this analysis by considering (1) the extent to which the polyunsaturated fat content of Promise affects serum cholesterol, (2) differences in the expected effects of various saturated fatty acids (such as stearic acid) on serum cholesterol, (3) the effect of dietary cholesterol on serum cholesterol, and (4) the direct effect of dietary cholesterol on heart disease independent of its effect through serum cholesterol.

The value of taste and texture differences between butter and Promise also merit consideration. Given the price and health disparities between butter and Promise, people would not be consuming butter unless it is superior on other attributes such as taste and texture. These differences are extremely difficult to measure. One way to deal with this problem is by allowing marketers to explain the health and price trade-offs to consumers and to then let consumers decide if the taste differentials are more important than these other differences.

Given the high probability that the claim is true, the small likely costs if the claim turns out to be false, and the large likely benefits if the claim turns out to be true, messages to reduce saturated fat would typically pass an expected value test today.

But What Kind of Cost/Benefit Analysis Could Have Been Performed Twenty-Five or Thirty Years Ago?

A critic could reasonably charge that the preceding example provides a limited illustration about the usefulness of an expected value analysis because it is based on a diet/health relationship about which substantial consensus has emerged. As a result, one might argue that the example does not apply to decision making when science is less certain. But the expected value rule was specifically designed to apply to such decisions. Less certainty just means that the probability of truth variable must be adjusted accordingly.

As an example of how the expected value framework might be applied when the science is less certain, we consider in this section how a policy analyst might have used an expected value framework some twenty-five or thirty years ago, when the evidence on diet and CHD was relatively young. A brief review of the early data indicates that a similar analysis could have

been conducted and that the estimated effects would have been strikingly similar.

It appears that a similar analysis could have been applied because data were available to estimate the two critical relationships used in the preceding analysis: namely, the relationship between saturated fat and serum cholesterol and the relationship between serum cholesterol and coronary heart disease.

The quantitative estimate of the effect of saturated fat on serum cholesterol used in the previous section comes from the "Keys" equation. According to this equation, a 1% change in saturated fat (technically, replacing carbohydrates on an iso-caloric basis) results in an estimated 2.7 mg/dl change in serum cholesterol. It appears that this estimate, although not without its limitations, represents the state-of-the art for estimating the effect of saturated fat on serum cholesterol.[142] Given the broad and current use of the Keys equation, one would think that it stems from the latest research. What may therefore be surprising is that this result did not first appear in the 1980s, the 1970s, or even the 1960s. Keys published this result in 1957.[143] Thus, an analyst would have had a basis for evaluating claims about saturated fat and serum cholesterol over thirty years ago. However, it may have been more controversial then.

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[142] In fact, this is one of two quantitative estimates of the relationship between saturated fat and serum cholesterol given in the Surgeon General's Report on Nutrition and Health (1988) at 97. The report lists two equations for estimating quantitative effects of changes in saturated fat on serum cholesterol, the "Keys" equation and the "Hegsted" or "Harvard" equation. (The Hegsted equation predicts that a 1% increase in daily calories from saturated fat results in a 2.16 mg/dl increase in serum cholesterol.)

[143] Keys et al. (1957).

As noted above, the NRC gleaned its estimate of the effect of changes in serum cholesterol on CHD from its review of all the evidence, which has certainly grown in thirty years. If an analyst had tried to obtain a similar estimate thirty years ago, there is a good chance that he would have relied on "new" (1957) results from the Framingham study of CHD[144]. We therefore consider how the results of this analysis can be transformed into an estimate of the effect of changes in serum cholesterol on CHD.

The Framingham study provided the following data relevant to the relationship between serum total cholesterol and the incidence of arteriosclerotic heart disease (ASHD)[145] for men aged 45-62:

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[144] Dawber et al. (1957) at 4-24.

[145] The Framingham study talks about "ASHD" while the NRC report talks about "CHD". The two terms are substantially similar, if not equivalent, and we therefore use the term CHD for both. ASHD (arteriosclerotic heart disease) includes certain myocardial infarction, likely myocardial infarction, angina pectoris (with sufficient symptoms to lead all observers to agree with this diagnosis), coronary occlusion (sudden death attributed to CHD), and myocardial fibrosis (death, with either clinical evidence of progressive cardiac failure in the absence of apparent cause, or with autopsy evidence of myocardial fibrosis which could be attributed to atherosclerosis of the coronary arteries). (Dawber et al. (1957) at 6-7.) The NRC definition of CHD is less precise, but the report notes that three syndromes, angina pectoris, myocardial infarction, and sudden cardiac death are included in the term coronary heart disease. (NRC (1989) at 19-3.)

	Population At Risk	New Disease	Rate/1000
All Persons	898	52	58
Cholesterol Measured at Examinations I or II			
260 mg/dl and over	172	21	122
225-259 mg/dl	265	12	45
Less than 225 mg/dl	445	18	40
Unknown	16	1	(not estimated)

A very rough estimate in a form comparable to that given in the NRC report can be gleaned from this table by asking how the data could be used to estimate the effect of 1% change in serum cholesterol on CHD. In particular, a conservative estimate is derived.[146] This estimation requires some further assumptions and manipulation, which are admittedly problematic. Nevertheless, analysts must work with incomplete information and the exercise is therefore still instructive.

Percentage changes cannot be calculated without knowing the range of the serum cholesterol values, which are not given in the report. (An early analyst might have been able to get this information from the study's authors.) Using general information, however, a rough estimate of the

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[146] Percentage calculations are somewhat arbitrary because two different bases can be used. As discussed further below, because we divide by the larger of the two bases to estimate this percentage decrease in heart disease from decreases in serum cholesterol, the estimated effect is conservative. In a more sophisticated analysis one might estimate the effect of a one percent change in serum cholesterol on heart disease by applying the available data to different functional forms.

range can be obtained.[147] The cholesterol categories are estimated to be 260-322 mg/dl, 225-259 mg/dl, and 139-224 mg/dl. The midpoint of each group is therefore estimated respectively as 291 mg/dl, 242 mg/dl, and 182 mg/dl. Moving from the high group to the middle group therefore results in a 17% decrease in serum cholesterol and a 63% reduction in CHD.[148] Roughly translated, a 1% decrease in serum cholesterol results in a 3.70% decrease in CHD. Moving from the middle group to the low group results in a 25% reduction in serum cholesterol and a 11% reduction in CHD.[149] Roughly translated, a 1% decrease in serum cholesterol results in a .44% decrease in CHD.[150]

The estimated effect of a 1% change differs substantially for the two groups. An analyst might therefore choose to keep them separate (in other

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[147] For men aged 45-54 years in 1960-62 the mean serum cholesterol level was 230.5 and the standard deviation was 45.6. (U.S. Public Health Service (1967) at 2.) If one assumes that the Framingham population is similar to the US population, these estimates can be used to estimate the range of serum cholesterol values. To estimate the upper level of serum cholesterol values we add twice the standard deviation to the mean (230.5 + 2(45.6) = 321.7). To estimate the lower level of serum cholesterol values we subtract twice the standard deviation from the mean (230.5 - 2(45.6) = 139.3).

[148] (291 mg/dl - 242 mg/dl) / 291 mg/dl = .17 and (122 - 45)/122 = .63.

[149] (242 mg/dl - 182 mg/dl)/242 = .25 and (45-40)/45 = .11.

[150] In contrast, estimates gained from using the smaller base are much larger. Moving from the low group to the middle group results in a 33% increase in serum cholesterol (242-182/182 = .33) and a 12% increase in heart disease (45-40/40 = .12). Thus, moving from the low group to the middle group a 1% increase in serum cholesterol is associated with approximately a .36% increase in heart disease (12/33 = .36). Similarly, moving from the middle group to the high group results in a 20% increase in serum cholesterol (291-242/242 = .20) and a 171% increase in heart disease (122-45/45 = 1.71). Thus, moving from the middle group to the high group, a 1% increase in serum cholesterol is associated with approximately a 8.55% increase in heart disease (171/20 = 8.55). A simple average using the smaller bases indicates that on average, a 1% increase in serum cholesterol results in approximately a 4.46% increase in heart disease (8.55+.36/2 = 4.46).

words, conclude that a linear relationship between serum cholesterol and CHD does not exist). In particular, an analyst might be conservative and base his decisions on the smaller of the two effects. Alternatively, an analyst might be curious about the "average" effect of a 1% change. Arbitrarily calculating a simple average, it can be estimated that a 1% change in serum cholesterol is related to in a 2.07% change in CHD.[151] It is curious how closely this conservative and simple average coincides with the much more recent NRC estimates.

The magnitude of estimated potential benefits of allowing Promise's claims approximately twenty five or thirty years ago could have been quite similar to the magnitude estimated today. The magnitude of the potential costs of allowing Promise's claims 25 years ago is more difficult to estimate. At the time there was undoubtedly concern about the potential for adverse affects on other diseases and special concern about special sub-populations, such as children and pregnant and lactating women. Moreover, there is no doubt that the estimated probability of "truth" about the diet-heart disease hypothesis was lower twenty-five or thirty years ago. According to the theoretical expected value model, however, if the likely costs of allowing the information was estimated to be equal to the likely benefits, then there only had to be a little more than a 50:50 chance that the diet-heart hypothesis was true in order to make the expected value of the information positive. And there is a good chance that this would have been the case, at least for a subset of possible claims.

Butter also cost more than margarine twenty-five or thirty years ago. In 1960, for example, margarine cost an average of 26.9 cents per pound and

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[151] A simple average is calculated as (3.70 + .44)/2 = 2.07.

butter cost an average of 74.9 cents per pound.[152] Thus, encouraging switches from butter to margarine would have yielded monetary savings, not monetary costs. An expected value analysis of claims about saturated fat and cholesterol claims for margarines may well have led to an earlier approval of health information in labeling.

This example was presented only to illustrate in very general terms how one might begin to fashion an expected value analysis for a concrete health claim. In practice, of course, the analysis would be reviewed and possibly revised by experts retained by the regulatory agency. Because the analysis is of a preliminary nature, it included several caveats to emphasize that the numbers used in the analysis are simply rough estimates. Hence, a reader might ask: "If the estimates are this rough in an area that has been studied extensively, wouldn't they be even more tenuous in younger research areas?"

The answer to this question is undoubtedly "yes." A reader may therefore further wonder if the analysis would be of any use when the science is less certain. We maintain that the expected value principles are useful even when the science is very uncertain. What we have presented is a simple conceptual framework for assessing when to allow health claims. Imbedded in the analysis is an explicit consideration of the likely harm that would arise if a prohibited claim turns out to be true. From our review of the health claims debate, we think that too little emphasis is given to this question. By forcing regulators to face it head on, we think that an expected value framework could improve decision making.

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[152] Riepma (1970) at 149.

D. Regulatory Problems from "Associative" and "Implied" Claims

The present controversy over health claims for foods was brought into focus by explicit claims of health benefits for a category of foods (those high in fiber) as part of a branded marketing campaign for a food in that category (All-Bran). A quite different category of health claims has often played an important role in the past and will continue to pose problems for regulators. These are claims formed by consumers themselves, by combining information in ads with information from other sources. Such claims must be considered when evaluating how a regulatory approach will work in practice. Information received by consumers from sources other than advertising has been called "ambient information." Claims formed from a combination of ambient information and advertised information have been called "associative claims."[153] An example of this process would start with advertising for chicken that says, "low in fat." Consumers may combine this claim with information from the federal government that reducing dietary fat may prevent cancer, and thus create a new claim that eating chicken helps prevent cancer.

Ambient information is the fundamental source of health claims for foods. It includes scientific findings on nutrition and the views of experts on how consumers should respond to diet and nutrition research. From the perspective of advertisers and food sellers, most ambient information arises spontaneously and is beyond their control.[154] From the perspective of

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[153] Ford and Calfee (1988).

[154] Food manufacturers can affect the flow of basic health information by conducting their own research or by funding research by others. Although (continued...)

health claims regulators, the critical characteristic of ambient information is its tendency to elicit "associative claims" i.e., claims that are inferred by consumers even if the marketer did not intend to make the claim. For example, some consumers might convert a claim that skim milk is relatively low in fat into a claim that replacing whole milk with skim milk may help in preventing heart attacks. Because ambient information is by its nature decentralized, a major part of what advertising regulation seeks to control -- the effect of seller information on consumer behavior -- lies partly beyond the control of regulator and seller alike.

Associative claims have played a major role in food marketing and, especially, marketing regulation. Virtually any claim that a product contains an ingredient widely believed to be nutritious, or lacks a component thought to be harmful, can result in an associative health claim. For example, as discussed in Section IV(D), the emergence of associative claims about cholesterol and saturated fat in the 1960s placed the FDA in a dilemma: either prohibit truthful nutritional content claims about cholesterol and saturated fat content (thus denying to consumers information their doctors were telling them was important) or allow associative claims about the effects of cholesterol and saturated fat and therefore allow, in effect, health claims for foods. After many years, the FDA finally settled on a policy of permitting at least some cholesterol content claims even when the claims

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[154] (...continued)
the funding source would not affect the outcome of well conducted research, it could affect the level of funding and therefore the rate of progress in obtaining new information. We noted earlier that one of the potential benefits of health claims in advertising is to increase the incentives to create information about food and health.

caused associative health claims. This was not the first such dilemma. The FTC had wrestled earlier with associative claims for low-tar cigarettes.[155]

Associative claims are different from "implied" claims, which are claims that are not stated but are reasonably implied by information in the ad itself. Associative claims require information from outside the ad, whereas implied claims arise purely from material in the ad. A major practical difference is that marketers have nearly complete control over implied claims, whereas a marketer sometimes would have to exert considerable effort to avoid making associative health claims. The lesser control of advertisers over associative claims raises significant regulatory problems, the most prominent being the question of when advertisers should be required to substantiate associative claims.

Analysis of techniques for determining when associative or implied health claims have been made lie beyond the scope of this paper. In general, however, the expected value approach is also applicable to such claims. Regulators must be careful not to restrict unnecessarily the dissemination of truthful, nonmisleading ingredient claims that help consumers identify products that best meet their dietary preferences, while taking into account the possibility that consumers might make detrimental changes in health behavior due to associative claims.

E. The Cost of Implementing an Expected Value Rule

One potential objection to the use of an expected value rule is that despite its other advantages, it would be more costly to implement than the past "bright-line" standard that prohibited most claims. A rule that

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[155] Calfee (1985).

explicitly requires a comparison of costs and benefits is admittedly more complex to administer than a rigid fixed consensus rule or an outright ban. This trade-off, however, is faced by virtually all regulators. For example, one could prohibit (or allow) all drugs, spending little if anything on the regulatory process itself. Few would advocate such an approach because the benefits of many drugs far exceed the cost of the regulatory process. The same argument applies here: some health claims will confer benefits that dwarf the increase in regulatory costs. Moreover, a process designed to weigh the costs and benefits of allowing health information about food is likely to be less costly than a process designed to weigh the costs and benefits of drugs. Common foods do not generally have the potential for causing the severe side effects sometimes wrought by drugs. Thus, the dangers from a decision that turns out badly are relatively modest. In addition, claims for foods tend to be based on ambient information that is relatively well known and discussed in the literature whereas new drugs are typically surrounded by more secrecy and uncertainty.

The costs of a regulatory process that allows claims must also be weighed against the costs incurred by the government to bring nutrition information to consumers. It may well be less expensive for the government to monitor marketing claims than it is for the government to mount its own marketing campaigns to inform consumers of nutrition recommendations by government agencies. This consideration was apparently one force behind the use of NCI findings in marketing materials for All-Bran.

Perhaps most importantly, one must consider the hidden costs of a consensus rule or an outright ban when comparing these strategies to an expected value rule. The ban, as discussed in detail, can impose severe

costs on society by limiting the amount of information available to consumers. A rigid consensus rule can impose similar costs. The consensus rule, however, also imposes additional costs: the costs of evaluating when a consensus exists. The administrative costs of a rigid consensus and expected value (or flexible consensus rule) may well be in the same ballpark.

VI. CONCLUSION

We support the FDA's move away from a ban on health information in food labeling. Even without such a ban, the market is likely to produce and disseminate less than the optimal amount of consumer information on diet and health. The ban only exacerbates this problem. It is not surprising that in this restrictive information environment consumers are often thought to be uninformed about nutrition and health. Lifting the ban on health claims is likely to improve the nutrition IQ of consumers and encourage the production of more healthful food products.

This paper does not question whether it is necessary and cost effective for the government to regulate health claims after the ban is lifted. Rather, given the widely perceived need for government regulation of health claims, we consider which of two likely regulatory strategies is likely to enhance consumer welfare the most. We conclude that a fixed consensus rule is less desirable than an expected value (or flexible consensus) rule.

This conclusion is based upon an application of the standard cost/benefit framework under conditions of uncertainty. The framework shows that if the likely benefits of allowing a claim that turns out to be true are equal to the likely costs of allowing claim that turns out to be false, there only has to be slightly more than a 50:50 chance that a claim will turn out to be true to make the expected value of allowing the claim positive. In contrast, fixed consensus rules generally require more than a 95:5 chance that a claim is true before it is allowed. A consensus rule therefore prematurely emphasizes harm from Type I regulatory error

(allowing claims about relationships that eventually prove to be false) over harm from Type II regulatory error (prohibiting claims that eventually prove to be true).

It does not appear that this premature emphasis on Type I error avoidance is appropriate for health claims about mainstream food products. A case history of prohibitions on health claims about saturated fat and serum cholesterol illustrates that Type II error is also important. Without evidence that Type I errors consistently impose greater costs than Type II errors, it is hard to see how consumers benefit from a ban or a rigid consensus standard.

Several possible objections to the use of an expected value rule merit consideration. One might argue that the expected value rule is too hard to implement. We find that the feasibility of an expected value approach has been demonstrated by the FTC's advertising substantiation standard, which is an application of expected value principles. Moreover, the FDA, as an agency with risk assessment expertise, is well equipped to employ an expected value rule. Finally, although the likely costs and benefits of allowing (or prohibiting) a claim cannot be measured very precisely, we think that regulators should be face the questions posed by the expected value framework before they prohibit information on the grounds that it has not been "proven" to be true. More specifically, it is important to focus not only on the probability that a message linking diet and health will turn out to be false, but to focus also on the likely harm that would occur if information about a relationship is prohibited, and the message turns out to be true.

One might also argue that resource constraints make the application of an expected value rule impossible. We believe that such an important policy should not be dictated by short-run resource constraints. Bans and rigid consensus rules bear hidden long-run resource costs which are likely to exceed the long-run costs of implementing an expected value rule.

Another argument against our proposal may be that it is old news, so it should be ignored. More specifically, one might counter that the FDA already bases its decisions on this standard cost/benefit framework. Although this is quite possible, it does not seem likely because the public debate has not focused on trade-offs between Type I and Type II error. Moreover, if this were the case, then it should be easy for the agency to follow our recommendation to make clear in its policy statement that the "weight of scientific evidence" necessary to support the use of health research findings in marketing messages will be determined by an expected value analysis. Otherwise, policy makers might find it too enticing to avoid controversy by maintaining the status quo through the use of a fixed consensus rule.

Explicitly requiring regulators to consider harm from Type I and Type II regulatory errors would not prevent the agency from taking a compromise approach. The FDA could use a flexible substantiation standard in most situations, while reserving the right simply to prohibit claims when a preliminary cost/benefit analysis indicates that the potential danger from a subset of claims is large, the science remains in substantial doubt, and the costs of careful assessment are high. This approach would still be a considerable improvement over a policy that always requires a high degree of consensus regardless of the consequences.

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