

HOW SHOULD HEALTH CLAIMS FOR FOODS BE REGULATED?
SUMMARY OF AN ECONOMIC PERSPECTIVE

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In September, 1989 the Bureau of Economics of the Federal Trade Commission released an Economic Issues paper on the regulation of health claims. Janis Pappalardo's conference presentation summarized the arguments made in that paper. What follows is the executive summary from the FTC report.

BACKGROUND

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.

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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.

REGULATING WHEN SCIENCE IS UNCERTAIN: CONSENSUS vs. EXPECTED VALUE RULES

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 policies 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.

Economic Incentives to Provide Accurate Health Information

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 manufacturers 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.

An Expected Value Rule Balances Type I and Type II Regulatory Error

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.

HARM FROM TYPE II ERROR

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.

FEASIBILITY OF AN EXPECTED VALUE RULE

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.

CONCLUSION

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.

REFERENCES

Calfee, John E. and Janis K. Pappalardo (1989). "How Should Health Claims for Foods be Regulated? An Economic Perspective." Federal Trade Commission, Bureau of Economics, Economic Issues Paper.