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October 25, 2002

Dockets Management Branch (HFA-30)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 02N-0209

Dear Madam or Sir:

This letter is submitted as a response to comments on FDA's Federal Register notice of May 16, 2002, on First Amendment issues. I will focus on issues affecting FDA's oversight of health-related claims for foods and dietary supplements.¹

Overview

I start from the perspective that the First Amendment is indispensable to American liberty and to the kind of free society we all want to have. Among its other contributions, the First Amendment fosters informed choice by citizens about all manner of things, political and public as well as personal and private. I also believe that providing consumers truthful, non-misleading information about the nutritional and health benefits of foods and dietary supplements can benefit public health to the extent consumers choose to use that information to construct healthier diets. FDA's role, as a public health regulatory agency, is to use the legal tools at its disposal to foster the flow of such information and thus help create an information environment around the marketing of foods and dietary supplements in which consumers can make informed choices and improve their health.

There is no fundamental conflict between this public health objective and the First Amendment. Indeed, the Supreme Court's rendering of the commercial free speech doctrine in *Central Hudson* provides FDA and the Congress all the room they need to

¹ I have worked on these issues as an FDA staff lawyer, a lawyer in private practice representing food companies, and as FDA's Deputy Commissioner for Policy during the rulemaking proceedings to implement the Nutrition Labeling and Education Act. I draw on that past experience in this letter, but I currently work in a non-profit research institution, Resources for the Future, where I have no professional involvement with the issues raised by FDA. This letter expresses my personal perspectives only and not the perspectives of any employer or client, present or past.

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devise policies that ensure the information consumers receive from commercial purveyors of foods and dietary supplements is truthful and non-misleading and facilitates meaningful consumer choice. It is abundantly clear from experience, however, that this requires strong and effective regulatory intervention by FDA. Neither the May 16 notice nor the comments I have read adequately acknowledge the underlying commercial reality that makes regulatory oversight and intervention necessary, and they do not propose affirmative strategies through which FDA could be more effective in fostering a flow of truthful, non-misleading nutrition and health information about foods and supplements that would benefit consumers. While it's a given that FDA must comply with emerging First Amendment jurisprudence, its focus should be less on the supposed constraints of the First Amendment and more on how it can make its regulatory interventions more effective in the interest of consumers and the public health.

Commercial and Public Health Reality

Food and dietary supplement companies exist to sell their products to consumers and earn a return for their investors. Food and supplement companies operate in a competitive environment in which they have strong economic incentives to identify and promote the benefits their products bring to consumers and to differentiate their products from those of their competitors. Their communications to consumers are intended and designed to attract customers and sell products. Since the mid-1980's, much of the food industry's promotional activity has focused on claimed nutritional and health benefits of products; and the very existence of the supplement industry is based on implied or express claims of such benefit. The marketing of foods and supplements based on claims of nutritional and health benefit responds to a powerful interest on the part of many consumers in protecting or improving their health through diet. At this intersection of the commercial motivation of companies and the personal health aspirations of consumers lies the potential for important public health good, which will be achieved to the extent consumers are empowered to choose products that deliver real benefit.

There are also dangers at this intersection. Even with the best of intentions, the commercial pressures on companies and the natural bias that comes with their commercial interest can result in the proliferation of product claims that are not fully substantiated, misleadingly presented, and in confusing conflict with claims on the same or similar products. Moreover, consumers have little ability to check the validity of claims for themselves. Consumers are rarely able to evaluate the scientific studies that support the claim and often will have difficulty assessing even their own possible benefit from the product, especially if the claim relates to reduction in the risk of a chronic disease.

The phenomenon of proliferating claims, uncertain substantiation, and loss of consumer confidence peaked for the food industry in the late 1980's, giving rise to enactment of the Nutrition Labeling and Education Act (NLEA) in 1990, which established criteria and regulatory procedures intended to ensure that claims are truthful,

non-misleading, and foster meaningful consumer choice. The NLEA controls include pre-market approval of disease-related health claims on foods and supplements, an intervention Congress concluded was justified by the health significance of such claims and their potential value as a tool for improving public health if consumers could rely on them as valid. NLEA's justification for pre-market review of disease-related health claims remains sound in today's environment.

In the supplement industry, the abundance of product claims appearing both on and off the label is well known. Some are sound; some are uncertain or misleading; and some are simply false. The Dietary Supplement Health and Education Act of 1994 (DSHEA) expanded the scope of the health-significant claims (specifically, structure-function claims) that could be made regarding supplements without prior FDA clearance. Partly as a result, the supplement industry has achieved rapid growth, yet it remains largely unknown whether and to what extent consumers have benefited.

The fact that there are strong commercial motivations to provide health-related information about foods and supplements and strong consumer interest in acting on such information creates opportunity for gain by sellers and consumers alike. This is what markets do, but markets fail when the information that prompts commercial exchange is false, misleading, or simply perceived to be unreliable. In the case of food and supplement products, market failure due to faulty information can cause more than economic harm. It can jeopardize the ability of consumers to make informed choices on matters of potentially great health significance. It is for this reason that FDA should be actively considering what it can do to foster the kind of information environment around the marketing of foods and dietary supplements that would empower consumers to make informed choices and improve their health.

Commercial Free Speech and the Question for FDA

The commercial free speech doctrine, as pronounced by the Supreme Court in the *Central Hudson* case, recognizes that commercial free speech – speech proposing a commercial transaction – stands on different footing under the First Amendment than political speech. We are generally free in political discourse to engage in the most freewheeling debate and expression of views, even if some of what we say is factually incorrect or misleading. Under *Central Hudson*, commercial speech that is false or misleading has no First Amendment protection. Moreover, the government can regulate even truthful and non-misleading commercial speech if the government's interest in such regulation is "substantial," the regulation "directly advances" the government's interest, and the regulation is "not more extensive than is necessary to serve that interest."

Even following the *Pearson* decision in the U.S. Court of Appeals for the D.C. Circuit, there is no doubt that the courts would consider "substantial" FDA's interest in ensuring that nutrition and health-related claims are truthful and non-misleading. Moreover, regulatory interventions requiring pre-market substantiation of claims, such as

required by NLEA and to a lesser extent by DSHEA, “directly advance” that interest. The only limitation imposed by *Pearson* on FDA’s pre-market approval of disease-related supplement claims was that FDA must allow claims accompanied by qualifying language in cases in which the data on the validity of a supplement-disease relationship are not conclusive, but then only if FDA concludes the qualified claim is not misleading.

Thus, under the law as it stands now, the crux of the question FDA should be focusing on is not whether it can prevent or prohibit misleading commercial speech or even whether it can impose regulatory controls, such as requirements for pre-market review, to ensure that product claims reaching the marketplace are neither false nor misleading. As far as the First Amendment is concerned, FDA can do all these things. To fulfill its public health mission, FDA should be asking instead how it can do this most effectively, in a way that advances the consumer’s interest in having access to information on the basis of which consumers can make meaningful choices.

The Regulatory Policy Issue and a Proposal

The nature of the information underlying most potential claims of nutritional or health benefit is such that there is, typically, room to debate whether the claim is truthful and non-misleading. Thus, the threshold regulatory policy issue is who should decide. Who should make the judgment, based on the available science, whether a claim is truthful and non-misleading? The proponent of the claim is not the best judge, because of the lack of objectivity that comes with a commercial interest and the fact that the proponent, by virtue of its knowledge and perspective, may in fact not be misled by a claim that would be misleading to others. For reasons noted earlier, the consumer is also in a poor position to judge whether an ostensibly science- and data-based claim is truthful and non-misleading. FDA, with its expertise, objectivity, and mandate to protect the consumer’s interest, should decide, or have a meaningful opportunity to examine claims before they enter the market.

For disease-related claims on foods and dietary supplements (“health claims” under NLEA), FDA currently does decide on the basis of a pre-market review of the available data, and this requirement should be maintained. For structure-function claims, the company decides, with FDA left to challenge a claim after the fact in a judicial enforcement context in which the agency bears the burden of proving the claim is false or misleading. DSHEA established a requirement for supplements that a company making a structure-function claim have substantiation for the claim and submit to FDA, within 30 days after the product enters the market, the wording of the claim but not the substantiation for it. FDA lacks the resources to examine a significant fraction of the many claims in the marketplace, review their substantiation, and, when a claim appears misleading, develop the evidence necessary to prove it in court.

For structure-function claims, an affirmative new effort and approach by FDA is needed to help correct the market failure present in the marketplace for products bearing

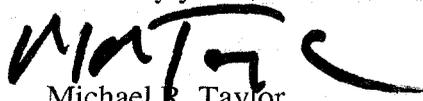
nutrition- and health-related claims and to compensate for the limitations on purely post-market approaches to regulation of claims. I propose that FDA establish a rigorous pre-market substantiation program for structure-function claims for foods and dietary supplements, modeled on the Federal Trade Commission's advertising substantiation program, but with the additional feature that the substantiation be submitted to FDA, together with a pre-market notification of the seller's intent to make the claim. FDA should establish criteria for what constitutes adequate substantiation and a misleading claim, and it should obtain the scientific review, monitoring and enforcement resources required to give the substantiation requirement teeth. This proposal would not involve pre-market approval of structure-function claims, but failure to submit adequate substantiation should be the basis for deeming a product misbranded. Implementing such a program would require additional resources as well as legislation to make the pre-market notification and submission of substantiation mandatory.

Conclusion

A rigorous claims substantiation and pre-market notification program for structure-function claims on foods and dietary supplements would go well beyond the current FDA effort to enforce the misbranding provisions of the Federal Food, Drug, and Cosmetic Act with respect to these claims. Some significant effort is justified, however, to prevent the food marketplace from slipping back into the chaos and confusion of the late 1980's and to correct some serious problems of false and misleading claims regarding supplement products in today's marketplace.

Significant effort to bring greater rigor to nutrition- and health-related claims is also justified by the important public health opportunity that could be lost if consumers lack confidence in the claims they see on product labels. Emerging science is pointing toward significant opportunities to improve health and reduce the risk of disease through diet, and there is significant commercial interest in marketing "functional foods." Consumers deserve protection from the economic loss associated with ineffective products, but they also should be provided reliable information on the basis of which they can choose effective products that will be beneficial to them. The unaided marketplace has proven itself unable to provide such information on a consistent basis. It is FDA's duty to correct this market failure. The First Amendment is not an obstacle to doing that.

Sincerely yours,


Michael R. Taylor
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