Remarks of J. Howard Beales

Before

The Food and Drug Law Institute

Conference on Qualified Health Claims

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"The views expressed by Mr. Beales are his own views and do not necessarily represent the views of the Commission or any individual Commissioner."

I am pleased to speak to you today between this morning's discussion of the history of health claims and this afternoon's discussion of their future. The inscription on the Archives Building across the street from my office reads "What Is Past is Prologue." Recent developments in law and policy have recognized that consumers and competition benefit from the dissemination of truthful and non-misleading

[1]H. Beales, R. Craswell, S. Salop, *The Efficient Regulation of Consumer Information*, vol. XXIV Journal of Law and Economics 491, 492 (Dec. 1981).

[2] G. Stigler, *The Economics of Information*

high-fiber cereals, and most significantly from a public policy standpoint, the greatest gains occurred among the least advantaged consumers.

The cereal market changed, too. The market share for high-fiber cereals increased by almost four percentage points, sales of high-fiber cereals increased by $280 million, and more high-fiber cereal products were introduced. Now I'm the first to admit that one case study is not definitive proof of the benefits of health claims.[4] But, as G.K. Chesterton once wrote, "the chirping of a single robin in the yard is some proof that spring has arrived."

For better or worse, government regulation may affect the extent to which companies make health claims. The NLEA essentially requires that food companies petition the FDA for approval prior to making health claims on food labels. The NLEA also states that the FDA cannot approve such a petition unless the claim is supported by "significant scientific agreement" among experts.

The existing NLEA requirements certainly provide a high level of protection against misleading claims - - an important goal of any consumer protection statute. But we also need to be concerned about their impact on the availability of truthful information. A study by the FTC's Bureau of Economics[5] examined a sample of 11,647 food ads that appeared in eight leading magazines between 1977 and 1997. The FTC study concluded that our experience under

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[4]Other studies have found significant reductions in fat consumption during the period when health claims were most prevalent. *Information and Advertising Policy: A Study of Fat and Cholesterol Consumption in the United States*, 1977 to 1990 at E-24 (1996).

[5]P. Ippolito & J. Pappalardo, *Advertising Nutrition and Health: Evidence from Food Advertising 1977-1997*, FTC Staff Report (Sept. 2002)

restrictions on health claims that had the *potential* to mislead consumers. As *Pearson v. Shalala*[8] and related cases make clear, the First Amendment embodies a "preference for disclosure over outright suppression."[9] The government cannot restrict health claims that have the potential to mislead unless the claims cannot be qualified to make them truthful and not misleading. The net effect of *Pearson*, and the more recent decision in *Whitaker*,[10] is that the government can prohibit health claims not supported by significant scientific agreement because such claims are likely to mislead consumers only if the government can prove that qualifiers

[8]164 F. 3d 650 (D.C. Cir. 1999), *reh'g en banc denied*, 172 F.3d 72 (D.C. Cir.1999).

[9] *Id*. at 658.

[10]*Whitaker v. Thompson*, 353 F.3d 947 (D.C. Cir. 2004).

My first point is that the proper treatment of "B" claims by the FDA is most critical because these claims are the most likely to have the most actual effect in the marketplace. Companies, of course, will choose to make claims that are most likely to help them sell their products, and "B" health claims are likely to have the most actual impact in the marketplace. These are claims that may not meet the significant scientific agreement standard, yet are supported by solid - - and often growing - - scientific support. Even with qualification, a strong selling message remains.

For example, there is accumulating evidence on the relationship between foods high in Omega 3 fatty acids - - like certain types of fish - - and reduced risk of heart disease. Based on this evidence, the American Heart Association has recommended that consumers increase their consumption of foods rich in these acids. A health claim for Omega 3 fatty acids and reduced risk of heart disease has not been allowed under the NLEA, because it does not appear to be supported by significant scientific agreement - - yet. But there is a real cost to consumers in holding this information back if, as we expect, it turns out to be true - - lives could be saved. If, under the FDA's new approach, the claim was considered a "B" claim, the agency would not challenge it so long as the marketer properly qualified the claim to convey that emerging (but not conclusive) scientific evidence supports the claim. Because companies are most likely to devote their scarce resources to making "B" claims, the FDA's regulatory determinations regarding these claims are likely to have the greatest impact. "B" claims are key.

Second, based on the FTC staff's experience conducting copy tests of ads, we know that disclaimers and qualifying language can work. They are most effective if they are clear and prominent, focusing on specific elements such as clarity of language, relative type size and

proximity to the claim being qualified, and an absence of contrary claims, inconsistent statements, or other distracting elements.[11]

But we also know disclaimers and qualifying language *do not always work*, particularly if they are intended to qualify the basic message of the ad - - that the product does what the ad says it does. We know, for example, that accurate information in the text may not remedy a false headline, fine print written disclosures may be insufficient to correct a misleading representation, other design elements may direct attention away from the qualifying disclosure, and *pro forma* statements or disclaimers may not cure otherwise deceptive messages or practices. Advertisers cannot say "X," qualifying it with a disclaimer that says "not X," and expect consumers to make much sense of it. Under FTC law, the advertiser bears the burden of ensuring that the qualification is adequate in placement, prominence and content. The risk of miscommunication is on the advertiser, not on the government and, most importantly, not on the public.

These are particularly problematic considerations in dealing with claims for which the supporting science is weak, especially "D" claims. It is certainly theoretically possible to qualify these claims adequately with the use of strong qualifying language conveying that the supporting science is weak. Such highly qualified claims, however, are seldom actually made in the marketplace, because they are unlikely to sell many products. Advertisers have limited amounts of space and they are unlikely to use it to inform consumers that there is only weak science showing that their products work. Moreover, the challenge of coming up with an adequate disclaimer falls to them, not the government. That unfortunately changes to some degree under

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[11]FTC Deception Policy Statement, appended to *Cliffdale Assocs., Inc.*, 103 F.T.C. 110, 176 n.7 (1984).