

Remarks of J. Howard Beales

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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 information, including health claims, in the marketplace. This is a very encouraging sign for those of us who remember when the debate over health claims under the Nutrition Labeling and Education Act (NLEA) commenced fourteen years ago; it focused not on whether the Food and Drug Administration (FDA) should permit qualified health claims, but whether the Federal Trade Commission (FTC) should prohibit them. I am optimistic that the recent past is but a prologue for a much more prominent role for health claims in improving consumer health. I would like to share with you the reasons for my optimism, along with a few caveats as we move forward with establishing a better system for making health claims for foods and dietary supplements.

So why has the FTC consistently over more than twenty years - - and through a succession of Democratic and Republican administrations - - advocated greater use of qualified health claims. Why? Much of the answer lies in the Commission's view of the power of a competitive marketplace to serve the interest of consumers and the important role of truthful information in ensuring that the marketplace is competitive.

Health claims are one type of product information that sellers convey to consumers, just like other information on labels and in ads. The dissemination of truthful and non-misleading information about the price, quality, and other attributes of products generally benefits consumers. Such information "allows buyers to make the best use of their budget by finding the

product whose mix of price and quality they most prefer.”¹ In short, advertising conveying truthful and non-misleading information can be, in the words of Nobel Prize-winning economist George Stigler, “an immensely powerful instrument for the elimination of ignorance.”²

Consumers also benefit from the increased competition resulting from the dissemination of product information by sellers. Such information allows buyers to locate a superior product for the same price, or a comparable product for a lower price. The ability of sellers to convey information thus provides a powerful incentive to innovate and improve the products that they offer. When sellers engage in such vigorous competition, it leads to increases in quality and decreases in prices.

This is a bit abstract, so let me give you a real world example involving a health claim for a food. Prior to 1984, health claims were not allowed on food labels. In 1984, however, the Kellogg Company began claiming that its All Bran cereal was high in fiber and that diets high in fiber could reduce the risk of cancer, a claim that was consistent with the National Cancer Institute’s longstanding recommendations. Competing cereal manufacturers responded to Kellogg’s health claim by making similar health claims for their own high-fiber cereals.

An FTC Bureau of Economics study evaluated the effect of this health claim on consumer cereal choices.³ By 1987, consumers had substantially increased their consumption of

¹H. 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*, 64 *J. Pol. Econ.* 213, 220 (1961).

³P. Ippolito & A. Mathios, *Health Claims in Advertising and Labeling: A Study of the Cereal Market*, FTC Staff Report (1989).

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 Economics⁵ 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

⁴Other 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).

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

the NLEA is consistent with the hypothesis that its labeling regulations have decreased health claims in food advertising.

For example, the sample revealed that heart disease and serum cholesterol health claims peaked in 1989, and then dropped substantially in the early 1990's following the passage of the NLEA. Likewise, since the passage of the NLEA, ads for fats and oils no longer make claims about the health reasons to choose one fat over another.

Such health claims convey real - - and important - - information that consumers want to know. There now is significant new information, including the FTC's enforcement experience and empirical studies, that the well-intended restrictions of the FDA have prevented consumers from receiving truthful and non-misleading health information.

These empirical findings dovetail with First Amendment cases which likewise reflect a growing recognition that government restrictions on truthful and non-misleading commercial speech, such as health claims, may harm consumers. The Supreme Court has held that "the free flow of commercial information" is indispensable so that the "economic decisions" of consumers can be "intelligent and well-informed."⁶ On the other hand, because it distorts the ability of consumers to make informed purchasing decisions, the Court has held that the First Amendment does not protect false or misleading information.⁷

Most commercial speech cases relating to health claims have not concerned government restrictions on claims that were false or misleading. Rather, these cases have addressed

⁶*Virginia Board of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748, 765 (1976).

⁷*In re R.M.J.*, 455 U.S. 191, 200 (1982); *Central Hudson Gas & Elec. Corp. V. Pub Serv. Comm'n*, 477 U.S. 557, 566 (1980).

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 would be ineffective in conveying the amount of science that supports the claims.

In response to the court decisions in *Pearson* and *Whitaker*, the FDA has embarked on a new approach to health claims - - the Consumer Health Information for Better Nutrition Initiative (“Health Claims Initiative”). On an interim basis, the agency is classifying all proposed health claims submitted for approval as being supported by a particular level of science, from A to D.

Scientists have a high level of comfort that the relationship behind “A” claims is valid, a moderate or good level of comfort that the relationship underlying “B” claims is valid, a low level of comfort that “C” claims will prove to be valid, and an extremely low level of comfort that the science supporting “D” claims will be shown to be valid.

The FDA has announced that it will continue to approve “A” health claims because they meet the significant scientific agreement standard for approval of an unqualified claim under the

⁸164 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).

NLEA. As a matter of prosecutorial discretion, though, the agency will no longer challenge B, C, and D health claims so long as they are appropriately qualified to be truthful and not misleading. The FDA recently issued a Federal Register Notice seeking public comment on adopting a permanent approach to qualified health claims, with one of the options being considered making these interim rules into final rules. The agency also sought consumer research bearing on issues related to qualifying claims. I anticipate that the FTC staff will file a comment with the FDA addressing - - in a general and preliminary way - - some of these issues.

The FDA should be applauded for its effort over the last year to develop improved approaches that allow consumers to receive more truthful and non-misleading information about the health implications of foods and dietary supplements. But FDA Commissioner McClellan also deserves credit for focusing on two fundamental principles in moving forward on health claims. First, he has underscored that the FDA wholeheartedly agrees that truthful and non-misleading information is beneficial to consumers and competition. Second, he has emphasized that FDA intends to rely on empirical evidence - - such as consumer research - - to guide the agency's decisions concerning health claims and other government regulations of speech. With these fundamental principles as a polestar, I am optimistic that the FDA will not veer off course in the future in its Health Claims Initiative.

For decades, the FTC has analyzed the adequacy of disclaimers and other qualifying language to limit advertising claims, including claims concerning the amount of supporting science. Drawing on this experience, let me make a couple of points concerning FDA's current efforts.

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

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

the NLEA's preapproval format, when government must specify a disclaimer that will always work for a category of claims, regardless of context. It is not clear that there is such a disclaimer that will work for all "D" claims.

The FDA's and FTC's ongoing consumer research is the most certain means of determining if consumers will take away a truthful and non-misleading impression from a health claim with a disclaimer or other qualifier. I therefore am pleased to see that the FDA is undertaking a substantial effort to test the disclaimers and other qualifiers that might accompany health claims to convey the level of supporting science. The FTC staff is conducting similar research that I hope we can complete and share in the near future. I would encourage private groups and companies to conduct and submit the same sort of consumer research to the FDA for its consideration. In my view, we should take advantage of this unique opportunity to help the FDA develop a regulatory scheme for qualified health claims that is based on solid empirical research and make sure it is one that works for consumers.

In conclusion, the FDA's evolution in its approach to health claims is likely to allow consumers to make better-informed choices about foods and dietary supplements. The agency should be congratulated for making changes in its approach to allow greater use of health claims and to ground its approach in empirical research. These are the right fundamental premises. Unanswered questions remain, but I am confident that these questions will be answered in a way that benefits American consumers.

Thank you.