

## MIXED RESULTS FOR FREE SPEECH IN FDA HEALTH CLAIMS GUIDANCE

by  
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Late last year, the Food and Drug Administration (“FDA”) announced in the Federal Register the availability of a “Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements (“the Guidance”).” 67 Fed. Reg. 78002 (Dec. 20, 2002). Although limited by its terms to food and dietary supplements, the Guidance has important implications for the pharmaceutical industry. This LEGAL OPINION LETTER briefly discusses the implications of the Guidance on how FDA interprets advertising claims.

Before determining speech to be false or misleading, the First Amendment demands that FDA adopt transparent and neutral evaluation procedures. *See* Comments of Pfizer Inc. on First Amendment Issues, FDA Docket No. 02N-0209 (Sept. 13, 2002) (“Comments”) at 56. This should include the use, as appropriate, of empirical methodologies (e.g. consumer surveys) for determining what message is communicated by a particular advertising claim. *Id.* In the Guidance, FDA largely adopts this view in the context of food and dietary supplement claims. Indeed, the agency acknowledges the similarity of misbranding provisions of the Federal Food, Drug, and Cosmetic Act that govern these products and those that apply to other regulated items, including drugs. 67 Fed. Reg. at 78003-04.

In the Guidance, FDA explicitly rejects use of “the ignorant, unthinking, and credulous” consumer standard as a yardstick for determining consumer deception, in favor of an ordinary person, reasonable consumer standard. *Id.* at 78004; Guidance at 6. In this respect, FDA explicitly states its intent to harmonize FDA’s policy on advertising interpretation with the policy followed by the Federal Trade Commission (FTC) in the FTC’s longstanding 1984 Deception Policy Statement. *Id.* at 78003; Guidance at 6. Indeed, FDA says that adoption of the reasonable consumer standard “more accurately reflects FDA’s belief that consumers are active partners in their own health care who behave in health

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promoting ways when they are given accurate health information.” 67 Fed. Reg. at 78004; Guidance at 6-7. This rationale for adopting the reasonable consumer standard dovetails with what the authors have argued is the empirically validated value of pharmaceutical advertising and its use as “an immensely powerful instrument for the elimination of ignorance.” See Comments at 4, citing Nobel Economics Laureate George J. Stigler, *The Economics of Information*, 64 J. POL. ECON. at 213 (1961).

According to FDA, its adoption of a reasonable consumer standard for interpreting advertising claims is also demanded by the First Amendment. Guidance at 6-7; 67 Fed. Reg. at 78004. As such, the agency acknowledges that the First Amendment “preclud[es] the government from regulating the content of promotional communication so that it contains only information that will be appropriate for a vulnerable or unusually credulous audience.” *Id.* citing *Bolger vs. Youngs Drug Prods. Corp.*, 463 U.S. 60, 73-74 (1983) (“the government may not ‘reduce the adult population . . . to reading only what is fit for children”). Adoption by FDA of a reasonable consumer standard for interpreting advertising claims not only harmonizes FDA’s approach with the FTC’s, it also brings FDA generally in line with how courts interpret advertising claims under § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a). See e.g. *United Industries Corp. vs. Clorox Co.*, 140 F.3d 1175, 1180 (8<sup>th</sup> Cir. 1998) (actionability of claim under § 43(a) depends on whether “reasonable buyer” would rely on it).

While FDA now correctly embraces the reasonable consumer standard for interpreting advertising claims, it takes a more equivocal position on the need for consumer survey evidence to prove the meaning of advertising claims. For example, FDA acknowledges that “surveys, copy tests, and other reliable evidence of consumer interpretation can be helpful in assessing the particular message conveyed by a statement that FDA believes constitutes an implied claim.” 67 Fed. Reg. 78003, n. 1; Guidance at 6, n. 1. Despite this recognition of the value of survey evidence, at least in the context of determining whether a claim in advertising is *implied*, FDA still argues that “the act does not require FDA to have survey evidence or other data before the agency is entitled to proceed under [the misbranding provision].” *Id.* Whatever are the *statutory* requirements for proof of consumer take away, strong reasons exist for concluding that the First Amendment mandates such empirical evidence in order for FDA to establish the existence of an *implied* claim.

For example, in a recent U.S. District Court for the District of Columbia ruling, *Whitaker vs. Thompson*, No. 01-1539 (GK) (D.D.C. Dec. 26, 2002), the court overturned the agency’s refusal to approve an appropriately qualified health claim because, among other things, “the FDA has failed to provide empirical evidence that an appropriate disclaimer would confuse consumers and fail to correct for deceptiveness.” Slip Opinion at 29 (citation omitted). The constitutional requirement that FDA adduce such empirical evidence before the claim could be suppressed outright bespeaks a judicial recognition that FDA, under the First Amendment, may not unilaterally decide questions of consumer deception at least where there is some ambiguity of meaning. The First Amendment likewise requires FDA to have some evidentiary basis—“empirical evidence”—about what a consumer take away from an ad before it may unilaterally determine the meaning of an advertising claim, at least where the claim is not expressly stated and is only arguably implied.